

[(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth [(b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_06232020.pdf

Start: 6/23/2020 1:00:00 PM
End: 6/23/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Vincent, Mike; Bascles, Lionel; Stein, Peter (FDA/CDER); Srinivasan, Badhri; Garner, Carlos; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manazine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue

Optional Attendees: Takas, Therese; (b) (6) Kenny, Dermot; Gonzalez, Nina; Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

Dear WG Colleagues, During the WG call we'll be talking about the **development of playbooks – priorities and volunteers!** We have received much positive feedback regarding the development of the first playbook for home nursing. Looking forward to this important discussion. Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 9/25/2020 5:00:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [(b) (6)] Cavaleri, Marco [(b) (6)] Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6)] Corey, Larry [(b) (6)] Culp, Michelle (NIH/OD) [E] [(b) (6)] Disbrow, Gary (OS/ASPR/BARDA) [(b) (6)] Dolsten, Mikael [(b) (6)] Erbeling, Emily (NIH/NIAID) [E] [(b) (6)]; Erck, Stan [(b) (6)] Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [(b) (6)] Hudson, Thomas [(b) (6)] James, Stephanie (FNIH) [T] [(b) (6)] Johnson, Robert (OS/ASPR/BARDA) [(b) (6)] Kramer, Lynn [(b) (6)] Lane, Cliff (NIH/NIAID) [E] [(b) (6)] Lepore, John [(b) (6)] Marks, Peter (FDA/CBER) [(b) (6)]; Marston, Hilary (NIH/NIAID) [E] [(b) (6)] Mascola, John (NIH/VRC) [E] [(b) (6)] Meeker, David [(b) (6)] Menetski, Joseph (FNIH) [T] [(b) (6)] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6)] Pandya, Hitesh [(b) (6)] Pao, William [(b) (6)] Parker, Ashley (NIH/OD) [E] [(b) (6)] Perlmutter, Roger [(b) (6)] Plenge, Robert [(b) (6)] Plump, Andy [(b) (6)] Rachel Ramoni [rachel. (b) (6)] Reese, David [(b) (6)] Rouse, Doris [(b) (6)] Santos, Michael (FNIH) [T] [(b) (6)] Skovronsky, Daniel [(b) (6)] Stein, Peter (FDA/CDER) [(b) (6)]; Stoffels, Paul [(b) (6)] Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Talley, Michael [(b) (6)] Tsai, John [(b) (6)] Vessey, Rupert [(b) (6)]; Virgin, Skip [(b) (6)] Wholley, David (FNIH) [T] [(b) (6)] Woodcock, Janet (FDA/CDER) [(b) (6)] Young, John [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Eric Hughes [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [(b) (6)] Lowy, Douglas (NCI) [(b) (6)] Read, Sarah (NIH/NIAID) [E] [(b) (6)] Victoria Davey [(b) (6)] Bancel, Stephane [(b) (6)] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene [(b) (6)] Paul, Steve [(b) (6)] Rasi, Guido [(b) (6)] Reed, John [(b) (6)] Desrosiers, Betsy [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [(b) (6)] Alvarez, Rosa Maria [(b) (6)] Margaret Anderson [(b) (6)] Appell, Evan [(b) (6)] Chen, Helen Q. [(b) (6)] Gonzalez, Nina [(b) (6)] Hawk, Harrison [(b) (6)] Mendelson, Jesse [(b) (6)] Stratton, Benjamin [(b) (6)] btolman [(b) (6)] Tountas, Karen (FNIH) [T] [(b) (6)]; Austin, Sarah (NIH/NIAID) [E] [(b) (6)]; Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)] Bell, Julie [(b) (6)] Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)] Carver, Trea (NIH) [C] [trea. (b) (6)] Caulfied, Anita [(b) (6)] Coan, Amanda [(b) (6)] Conrad, Patricia (NIH/NIAID) [E] [(b) (6)] Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)] Edl, Susan [(b) (6)] Fuhrer, Nicole [(b) (6)] Giorgi, Sara [(b) (6)] Hoban, Michelle [(b) (6)] Hoffstetter, Renata (FNIH) [T] [(b) (6)] Iberdemaj, Vaide [(b) (6)] Jenkins, Christine S. [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Lever, Susan [(b) (6)] McManus, Ayanna (NIH/OD) [E] [(b) (6)] Minnich, Beth [(b) (6)] Perala, Mie [(b) (6)] Protasiewicz, Ann [(b) (6)] Riccobene, Kim [(b) (6)] Riffin, Mary [(b) (6)] Ripley, Nadege [(b) (6)] Schuster, Donna [(b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6)] Simon, Dina (NIH/OD) [C] [(b) (6)] Suhana, Tina (NIH/VRC) [E] [(b) (6)]; Thomas, Ashley (FDA/CDER) [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6)].gov]; Anderson, James (NIH/OD) [E] [(b) (6)]; Burklow, John (NIH/OD) [E] [(b) (6)] Carluccio, Dana [(b) (6)] Castillejos, Carlos [(b) (6)] FNIH Central Account [(b) (6)] Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Myles, Renate (NIH/OD) [E] [(b) (6)]

(b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) ; Togashi, Mieko (NIH/NCI) [E]
(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica
(b) (6) Plenge, Robert [(b) (6) Vessey, Rupert [(b) (6)
Regan, Donna M (b) (6) Sorosa, Alex [(b) (6) Connelly, Sarah
(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; John Lepore
(b) (6) Grant, Sarah [(b) (6) Qashu, Felicia (NIH/OD) [E]
(b) (6)]; Wachtel, Jonathan (b) (6) Hamilton, Nancy
(b) (6)

Subject: ACTIV Leadership Call #10

Location: <https://fnih.zoom.us/> (b) (6)

Start: 11/19/2020 5:00:00 PM

End: 11/19/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; (b) (6) Davey, Victoria

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Plenge, Robert; Hamilton, Nancy; Vessey, Rupert; Regan, Donna M; Sorosa, Alex; Connelly, Sarah; Lowy, Douglas (NIH/NCI) [E]; John Lepore; Grant, Sarah; Qashu, Felicia (NIH/OD) [E]

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/16/2020 10:28:42 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)
Subject: ACTIV Therapeutics-Clinical Master Protocol Subgroup - Meeting #3
Location: https://fnih.zoom.us/j/ (b) (6)
Start: 4/20/2020 6:00:00 PM
End: 4/20/2020 7:00:00 PM
Show Time As: Busy
Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER)

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear TX-Clinical Master Protocol Subgroup,

This will be our 4th meeting. We will update with materials closer to the meeting.

Thanks,

Stacey

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From: Connelly, Sarah [(b) (6)]
Sent: 11/9/2020 9:42:43 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
 (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi
Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio
[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6) (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Hi All,

While not unanimous, more people were able to make the original meeting time than the Thursday option. We will therefore go ahead and keep the preclinical WG meeting on Wednesday at 10 AM ET.

Thanks,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

From: Connelly, Sarah

Sent: Friday, November 6, 2020 8:29 AM

To: Menetski, Joseph (FNIH) [T] < (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]

< (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) Baric, Ralph < (b) (6)

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) Colvis, Christine

(NIH/NCATS) [E] < (b) (6) Hewitt, Judith (NIH/NIAID) [E] < (b) (6) Deming, Damon

(FDA/CDER) < (b) (6) (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6)

(b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) Rao, Srinivas

< (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar

< (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6)

Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]

< (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6) (b) (6)

Cc: Diamond, Michael < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher

(NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Desrosiers, Betsy
< (b) (6) Eric Hughes < (b) (6) Jansen, Kathrin
< (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)
< (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)
Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)
[T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman,
Brett < (b) (6) Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes
< (b) (6) Rose Li < (b) (6) Dana Carluccio
<dana.ca (b) (6) Lagos, Enrique (NIH/NCATS) [E] < (b) (6) Jonson, Samantha
(NIH/NCATS) [E] < (b) (6) Gonzalez, Nina < (b) (6) Simon, Dina (NIH/OD) [C]
< (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D
< (b) (6) Dave Frankowski < (b) (6) Baric, Toni C
< (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) Florence, Clint (NIH/NIAID) [E]
< (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin < (b) (6)
Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)
Hawk, Harrison < (b) (6) Mason, Stephen < (b) (6)
(b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical working group,

Next week's full working group meeting falls on Veterans Day. Would the group prefer keeping the meeting on Wednesday at its regularly scheduled time or moving it to 10-11 ET Thursday, Nov 12, 2020?

Can you please let us know which of these options work for you. We will move the meeting to the most popular option.

Best regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6)

(b) (6) Baric, Ralph; (b) (6); Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6);

(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6); Connelly, Sarah;

(b) (6)

Subject: ACTIV Preclinical full working group

When: Thursday, November 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/1234567890> (b) (6)

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/j/1234567890> (b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

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(b) (6)

US (Germantown)

US (Chicago)

Dial by your location

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JS (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

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Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us/j/1234567890> (b) (6)

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v.E.1

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/18/2020 6:34:48 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: A Couple Articles of Interest

Attachments: International_Survey_to_Establish_Prioritized.95532 (1).pdf;
Core_Outcomes_Set_for_Trials_in_People_With.95535.pdf

Dear ACTIV TX-Clinical WG Members,

Please find attached a couple of articles that maybe of interest to this team summarizing some information on COVID trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

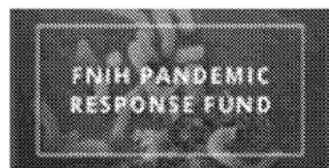
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/22/2020 8:32:31 PM
To: Vincent, Mike [(b) (6)] Bascles, Lionel [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Srinivasan, Badhri [(b) (6)] Garner, Carlos [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James [(b) (6)] Ferguson, Sue [(b) (6)]
CC: Takas, Therese [(b) (6)] [(b) (6)] Kenny, Dermot [(b) (6)] Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Wachtel, Jonathan [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Hill, Zoe (NIH/NHLBI) [C]

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(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora
[(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_06232020.pdf
Location: [https://fnih.zoom.us/\(b\)\(6\)](https://fnih.zoom.us/j/(b)(6))

Start: 6/23/2020 1:00:00 PM
End: 6/23/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday from 9:00 AM to 10:00 AM
Required Attendees: Vincent, Mike; Bascles, Lionel; Stein, Peter (FDA/CDER); Srinivasan, Badhri; Garner, Carlos; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue
Optional Attendees: Takas, Therese; (b) (6) Kenny, Dermot; Gonzalez, Nina; Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvevsson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

Dear WG Colleagues, During the WG call we'll be talking about the **development of playbooks – priorities and volunteers!** We have received much positive feedback regarding the development of the first playbook for home nursing. Looking forward to this important discussion. Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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(b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US
(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tomas Cihlar
[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin
[(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
[(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Lowy, Douglas (NIH/NCI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Louise Pitt
((b) (6) [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
[(b) (6) Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Hild, Sheri (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]

Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_20200522_d1.pptx; Animal Model Summaries.zip

Hi all,

Please find attached some materials to aid in our discussion today.

- * The first attachment contains the agenda as well as our WG's objectives and timeline.
- * The second attachment is a folder with the Animal Model 'one-pager' summaries.

Please let us know if you have any questions. Look forward to our discussion tomorrow.

Best,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: (b) (6) Menetski, Joseph (FNIH) [T]; (b) (6) (b) (6)
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Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter
(OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Tomas Cihlar; Qashu, Felicia (NIH/OD) [E]
Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey
(FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E];
Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy,
Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt ((b) (6) Pitt, Margaret L CIV USARMY
MEDCOM USAMRIID (USA); Nancy Haigwood; Gadbois, Ellen (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 22, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us> (b) (6)

Holding time

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To: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [(b) (6) Srinivasan, Badhri [(b) (6) Wachtel, Jonathan [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [(b) (6) Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Minnich, Beth [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Garner, Carlos [(b) (6)

Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [(b) (6)]; Hamilton, Nancy [(b) (6)]; Anderson, Margaret [(b) (6)]

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05052020.pdf; Network survey responses 04 May 2020.pdf; Site survey responses 04May2020.pdf; DRAFT CRO survey.docx

Location: <https://zoom.us/> (b) (6)

Start: 5/5/2020 1:00:00 PM

End: 5/5/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Stein, Peter (FDA/CDER); Vincent, Mike; Woodcock, Janet (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Bascles, Lionel;

Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Anderson, Margaret; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T];

Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Garner, Carlos; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues,

Attached is the meeting agenda along with current survey results (40 networks and 463 sites to-date!). In addition, attached are draft questions to consider for the CRO survey that will be discussed, but please note that some questions are carried over from the network survey for consideration (editing or deleting). Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

APAR0000020027-2515330

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(b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/8/2020 6:35:51 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

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Subject: Slides from ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201008.pdf

Dear ACTIV TX-Clinical WG,

Apologies for not getting these out ahead of the meeting, but please find attached the slides from today's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Subject: ACTIV Vaccines Working Group meeting

Location: <https://nih.zoomgov.> (b) (6)

Start: 2/18/2021 7:00:00 PM

End: 2/18/2021 8:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell

(b) (6) (b) (6) Cavaleri Marco; (b) (6)

(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,

Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];

Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan

(OS/ASPR/BARDA); Jim.Tart (b) (6) (b) (6) ; Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen

(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)

(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Embry, Alan (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E];

Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T];

Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,

Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Desrosiers, Betsy; Hughes,

Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman;

Gonzalez Lopez, Antonio; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR

(USA); Kathleen Neuzil; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra

(CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD);

Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Sotir, Mark (CDC/DDID/NCIRD/DVD); Thornburg, Natalie

(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;

(b) (6) Bethany Stokes; Kathleen Callahan; Molloy,

Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin;

Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary (NIH/NIAID) [E]; FNIH; Barton

Haynes, M.D.; Nelson Michael; Gilbert PhD, Peter B; Bloom PhD, Jesse D; (b) (6) Christopher Murray;

pennym; Alex Sigal; Ho, David D.; Offit, Paul; Randy Hyer; Adam Bloomfield; Gale Smith; Florence, Clint (NIH/NIAID)

[E]; (b) (6) ; Wan, Kanny (NIH/NCATS) [C];

(b) (6)

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Passcode: (b) (6)

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/1/2020 1:51:32 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) ; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

DTRA RD (USA) (b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)]
(b) (6)
CC: Chen, Helen Q. [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Assistance Needed with 2nd ACTIV/OWS mAb Scientific Summit - SMEs recommendations
Attachments: mAb Scientific Summit expert input request_vShare.pptx

Dear ACTIV Therapeutics-Clinical WG,

I hope you're doing well. I am reaching out to let you know, OWS, NIH, and ACTIV are hosting a mAb scientific summit mid to end of August. The objective of the summit is to facilitate discussion on mAb science and address how to optimize development and therapeutic use of mAbs going forward.

The summit will be facilitated in a panel format, with each panel focused on a white paper written and circulated in advance on a key topic in the space. We have attached a few slides capturing the key topics and the white paper format.

We are writing to you today to get your recommendations on experts that may be able to address each of the key topics, with a focus on 3 roles:

1. White paper author: Expert to write a paper providing an overview of the various positions on specific key topics in advance of the summit
2. Panelist: Additional experts to provide alternative perspectives on a panel during the summit to include industry partners
3. Moderator: Facilitator to develop questions for the panel and synthesize positions from white paper author and responses from panelists after the summit

We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel.

If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

Foundation for the National Institutes of Health

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/8/2020 6:32:49 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6)]; Vincent, Mike [(b) (6)]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kenny, Dermot [(b) (6)]; Wachtel, Jonathan [(b) (6)]
Subject: CT Capacity WG agenda and survey Dashboard review
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_06092020.pdf

Dear Clinical Trial Capacity Working Group,

Attached is the agenda for the full WG call tomorrow.

Please note that there will be some time to provide feedback regarding the Network/Site/CRO/SMO dashboard. I encourage all of you to take a few moments to review the dashboard ahead of the call tomorrow. Please think about additional features that will make this more user-friendly and more useful. The Deloitte dashboard team is very responsive to requests that can be accommodated by the Tableau platform.

Dashboard link: <https://analyticsqa.niaid.nih.gov/#/site/ACTIV/views/ACTIVCTCWGSurveyDashboard/Network-SiteMap?iid=1>

Many thanks!
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
[(b) (6)] | fnih.org

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 9:56:17 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6)]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] (b) (6) .gov]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [(b) (6) ; Pangalos, Mene [(b) (6) ; Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6)]; Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Anderson, James (NIH/OD) [E] [(b) (6)]; Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Lumsden, Joanne (NIH/NCATS) [C] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen [(b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6) Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Wachtel, Jonathan [(b) (6)]; Meltzer, Abbey (FNIH) [T] [(b) (6)
CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) ; Carver, Trea (NIH) [C] [(b) (6) Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Lever, Susan [(b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [(b) (6) Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6)]; Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Suhana, Tina (NIH/VRC)

[E] [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD)
[E] (b) (6)]; Togashi, Mieko (NIH/NCI) [E] [(b) (6) Underwood, Nancy
[(b) (6) Zottoli, Jessica [(b) (6) Hughes, Karen (NIH/OD) [E]
[ka (b) (6) Regan, Donna M [(b) (6) Plenge, Robert [(b) (6)

Subject: ACTIV Leadership Team Call #15

Location: [https://fnih.zoom.us/](https://fnih.zoom.us/j/9181234567) (b) (6)

Start: 4/28/2021 12:30:00 PM

End: 4/28/2021 2:00:00 PM

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Required Attendees: Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]

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Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Sharpless, Norman (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=340F3D07B6644DA7ACA53AB83DC066EF-SHARPLESSNE]
Sent: 5/15/2020 2:37:35 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19

Thx for sending

This is the sort of scientific effort that the NCI wishes to support with the Serology centers of excellence that we will be funding, and I will make sure they see our FOAs.

I think having an academic site doing testing for the clinical trials of ACTIV and then holding what I think would be CCI would be problematic, and these capacities for antibody detection and neutralization assays exist within the USG.

Ned

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:27 PM
To: Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Sharpless, Norman (NIH/NCI) [E] <(b) (6)>
Subject: FW: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19

In case this is of interest.

-----Original Message-----

From: Ed Scolnick <(b) (6)> >
Sent: Thursday, May 14, 2020 8:58 PM
To: Marks, Peter (FDA/CBER) <(b) (6)> Daniel Wattendorf <(b) (6)>
<(b) (6)> Emilio Emini <(b) (6)> Fauci, Anthony <(b) (6)>
(NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Tal Zaks <(b) (6)>
Cc: Iander <(b) (6)> Deb Hung <(b) (6)> >: Ramnik Xavier <(b) (6)>
<(b) (6)> Schreiber, Stuart <(b) (6)> David R. Liu <(b) (6)>
<(b) (6)> Ben Cravatt <(b) (6)> Michael Rosbash <(b) (6)> >;
Thomas Cahill <(b) (6)> Michael Z Lin <(b) (6)>
Subject: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19

Hi to All: For the past few days, I have been working with Dr Deb Hung a Member of the Broad Institute. Deb has been a member for 15 years and is a pioneer in Infectious disease. As the memo indicates, she had developed 2 assays which will be invaluable for the current Corona Virus Vaccine effort and is almost finished developing a 3rd one as noted in this memo. Having these assays can potentially if trials go as planned lead to an approval of vaccines by the Fall. This would be analogous to Rapid approval of Cancer therapies. Additional studies would go on but early use of the Vaccine to stem the pandemic would be possible and would be a spectacular achievement for the Biomedical community.

The Broad is capable of running all the assays, sharing that data with the FDA which is supportive of the effort and keeping each company's data confidential from other companies. The Broad has proved that it can do high throughput assays in its genotyping, sequencing and PCR based work and can now extend this capability to the immune assays needed to help the National vaccine effort

We urge you to approve this effort rapidly. In the HIV effort when I was at Merck we organized a Company consortium of 12 companies to share phase 2 data without showing structures of antiviral compounds. That allowed 2 companies to begin combination therapy 5 years earlier than normal and led to the triple therapy regimens that changed the face of HIV from a death notice to a manageable disease. This proposal can do the same for this pandemic.

I have included Katharine Jansen on the "to" list but am sending it to her private email address.

COLL0000021963-2515340

I implore you to help activate this effort as fast as possible free from the usual bureaucratic barriers. The effort can help the companies and most importantly help human beings who are terrified of becoming infected and prevent a second wave of infections in the fall, an event which would decimate the public and the country.

You can reach me by email or by cell phone (b) (6). I will make myself available and so will Deb Hung to answer your questions

Best wishes Edward Scolnick

From: Lowy, Douglas (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1B7B8FE4739478BB17840C56902718A-LOWYD]
Sent: 7/3/2020 4:16:20 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Gallo and OPV

Thanks, I'm on it! Doug

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>
Date: Friday, July 3, 2020 at 12:15 PM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)>
Cc: "Wholley, David (FNIH) [T]" <(b) (6)>
Subject: RE: Gallo and OPV

Doug:

There are several people with whom you could discuss this: Barney Graham (VRC/NIAID), Paul Offit (University of Pennsylvania), Richard Whitley (UAB), Larry Corey, Cliff lane, among others.

Best,
Tony

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Friday, July 3, 2020 12:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)>
Subject: Re: Gallo and OPV

Thanks, Tony. Can you suggest one or two people with whom I can discuss the issue? Doug

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>
Date: Friday, July 3, 2020 at 12:07 PM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> >, "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)>
Cc: "Wholley, David (FNIH) [T]" <(b) (6)>
Subject: RE: Gallo and OPV

This issue will not go away and so perhaps it is best to have the ACTIV Vaccines WG take a look at this and make some sort of recommendation.

COLL0000018273-2515341

From: Lowy, Douglas (NIH/NCI) [E] (b) (6)
Sent: Friday, July 3, 2020 11:54 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); Mascola, John (NIH/VRC) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6)
Subject: Re: Gallo and OPV

Hi Francis: The vaccine working group has not discussed this topic. Doug

From: "Collins, Francis (NIH/OD) [E]" (b) (6) >
Date: Friday, July 3, 2020 at 11:46 AM
To: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>, "Lane, Cliff (NIH/NIAID) [E]" (b) (6), "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)>, "Mascola, John (NIH/VRC) [E]" <(b) (6)>
Cc: "Wholley, David (FNIH) [T]" <(b) (6)>
Subject: RE: Gallo and OPV

Hi Tony, Cliff, Doug, and John (and looping in David)

Bob Gallo is back with a complaint that no one has followed up on the OPV idea. See attached. Was this discussed in the ACTIV Vaccines WG or in any other venue?

Tx, Francis

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >
Sent: Sunday, May 3, 2020 1:45 PM
To: Lane, Cliff (NIH/NIAID) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>; Mascola, John (NIH/VRC) [E] <(b) (6)>
Subject: RE: Gallo and OPV

Totally agree with Cliff's advice.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

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From: Lane, Cliff (NIH/NIAID) [E] (b) (6)
Sent: Sunday, May 3, 2020 1:22 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Lowy, Douglas (NIH/NCI) [E] (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6); Mascola, John (NIH/VRC) [E] (b) (6)
Subject: Re: Gallo and OPV

Francis,

I am not sure you need any sort of detailed response. I would just send a thank-you and indicate you will be sure those working on this at NIH are aware.

Cliff

On May 3, 2020, at 12:55 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi all,

I'm a bit at a loss to know how to respond to Bob Gallo. The aggressive manner in which he is promoting OPV causes me to worry he has lost objectivity about its promise. But is there any chance he has something here that could work?

Francis

From: Gallo, Robert (b) (6)
Sent: Sunday, May 3, 2020 12:07 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Your query to Dr. Kadlec

Dear Francis,

It was a pleasure to hear from you, and yes, it has been a long time since we met or even spoke. Moons ago I was set to write to you after reading your wonderful book, but I ended up instead speaking with others about it. I should add at this point that I did not quickly respond to your email of a few days ago because I simply missed it.

It is true that I strongly suggest that OPV be quickly (already it is not quickly) brought forward for induction of a strong innate immune response to prevent or markedly reduce SARS-CoV-2 infection and/or severity until the field obtains a proven safe and efficacious vaccine producing a long lasting, adaptive immunity. OPV is very safe (notably for OPV 1 and 3 as bOPV which we will use and completely safe in a vaccinated population), simple, cheap, rather obvious, yet unique among the massive number of vaccines many (maybe most) of which are the same or at least if not exactly the same aiming at the same mechanism (targeting the spike and searching for the putative correlate of neutralizing Abs.).

OPV should work for a few months and possibly longer. Also it should be working multiple times so I think could cover more than a few months, giving us time for a proven vaccine of adaptive immunity, which might be very long lasting as is hoped.

In the main the WHO comments are correct. Of course we sought and have letters of support from them as well as from many others. Though they are again supportive in their notes to you, there is one item that surprises me. They add that there was no clinical efficacy results as yet. They know or certainly should know that there is plenty of clinical data for this concept with BCG, OPV, and live Measles vaccine. Needless to say this is what turned me on during our regular Global Virus Network (GVN) conference calls. (Incidentally GVN is an organization I have thought of bringing to your attention. I think you would find it impressive and useful). I would be happy to share with you the clinical observations with OPV if you wish.

I would like to take a small diversion, but I suspect you are aware of these things. My colleagues and I respect the WHO because of its representation and because we have colleagues/friends there as well. However, sometimes bureaucracy of a massive degree leads to inaction or even much worse-- political expediency. I won't bother you with details of these unless you ask, but I had such experiences with HTLV-1 which we discovered in 1980 as the 1st human retrovirus and which cause not only the highest incidence of cancer (% of infections) of any virus and other fatal diseases as well but mainly in less developed countries (plus Japan) and again with HIV in 1984. Behavior was not beneficial. Perhaps it will be of relevance in the future because a few at WHO took a position to remove OPV (Sabin) in favor of IPV (Salk) in their polio eradication scheme. It was a huge failure. As my FDA collaborator, Konstantin Chumakov, says "Blessed be Bill Gates" because he saved OPV and saved the day and in so doing has produced a still better OPV.

There is indeed data also for BCG as well as live Measles though I know less of the latter. BCG is less available, requires injection, harder to make, not as safe, and we think unlikely to be as effective as OPV. Nonetheless, we favor its use too. The mechanisms will be similar.

You asked whether monkey trials are planned. For several reasons definitely not --though we are planning some monkey experiments, but not large enough for "clinical" conclusions. The main reasons are: 1) cost; 2) that billions not thousands or millions have received OPV safely and in our collective view (and we know the studies pretty well) protection has been clinically shown; 3) In a pandemic we wished to move quickly (so far we must say that has not been achieved). A typical monkey vaccine study will take time, but 4) in this case it would be a huge amount of lost time as monkeys require great doses of polio for infection and monkeys have to be trained to drink their orange juice. It would be hard to imagine that such studies would even give us useful information.

On a final digression Francis I have had 36 years of on/off experiences with glycosylated spike proteins--their analyses immunologically and especially regarding use in vaccines and developing neutralizing Abs. I believe it will be a mistake to put most eggs in that basket. The risks: shortened antibody half life; 2) protection NOT correlating with neutralizing Abs; 3) sometimes hazards from them. Admittedly, they might work, but I trust and hope that not everything is going in this bag. If you wish to discuss this again I will be available.

Finally, I had no idea you were into vaccines or SARS-2 nor any part of CoVID-19 disease, but I am very happy to learn this.

Thanks.

Bob Gallo

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, April 30, 2020 5:00 PM
To: Gallo, Robert (b) (6) >
Cc: Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Kadlec, Robert (OS/ASPR/IO) (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Shuy, Bryan (OS/ASPR/IO) < (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6)
Subject: Your query to Dr. Kadlec

CAUTION: This message originated from a non UMB, UMSOM, FPI, or UMMS email system. Whether the sender is known or not known, hover over any links before clicking and use caution opening attachments.

Dear Bob,

It's been quite a while since we've chatted. Bob Kadlec asked me to respond to your query about the possible use of OPV to activate innate immunity and provide COVID-19 protection. Has this been tested in a non-human primate model? I note the recommendation below that says a clinical trial is planned – can you tell me more about that?

As you can imagine, we are all flat out on the vaccine development pathway!

Francis

The use of oral polio vaccine (OPV) to prevent SARS-CoV2 (Polio Eradication Campaign)

There is no evidence that oral poliovirus vaccine (OPV) protects people against infection with COVID-19 virus.

A clinical trial addressing this question is planned in the USA, and WHO will evaluate the evidence when it is available.

In the absence of evidence, WHO does not recommend OPV vaccination for the prevention of COVID-19. WHO continues to recommend OPV as part of essential immunization services to prevent poliomyelitis and as part of global polio eradication efforts.

There are experimental signals from various studies over the years that OPV has non-specific effects on the immune system. These effects have not been well characterized and their clinical relevance is unknown. Such non-specific effects may not be limited to OPV, as other live vaccines have also been associated with non-specific protective effects (such as BCG vaccine against tuberculosis). Nonlive vaccines in contrast do not seem to have the same effects.

The exact mechanism of non-specific protection induced by live vaccines needs to be elucidated further. Clinical studies could begin immediately because the vaccines in question are licensed and have an excellent safety record. Clinical trials involving off-label use of various drugs licensed for other indications are currently underway. The existing scientific rationale suggests that the same should be done for OPV and other live vaccines. A study is currently being discussed with various partners and vaccine manufacturers, including the US FDA, the

outcomes of which will be carefully assessed to determine potential use in the context of the spread of SARS-CoV2 until the time when specific vaccines and antiviral therapies are ready.

From: Kadlec, Robert (OS/ASPR/IO) (b) (6)
Sent: Thursday, April 30, 2020 10:28 AM
To: Gallo, Robert (b) (6) >; Collins, Francis (NIH/OD) [E] < (b) (6)
Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Shuy, Bryan (OS/ASPR/IO)
< (b) (6)
Subject: Re: Response

Dr Gallo thank you for your note and I appreciate you reaching out to me. I have copied Dr Collins and Dr Tabak to consider the ACTIV forum they have created to bring industry academia and government to consider scientific base approaches That you have described. Dr Collins has organized a vaccine group and I assess could be the best and fastest place to discuss your concept. I am sure they will connect with you soonest

Best

Bob Kadlec.

Sent from my iPhone

On Apr 30, 2020, at 10:02 AM, Gallo, Robert (b) (6) > wrote:

Dear Dr. Kaldec,

I have not heard from you in over a week. You mentioned getting back to me in a day or two. Time is passing. I am asking you to look at OPV 1 plus 3 serotypes as a bivalent, completely safe vaccine with powerful stimulation of innate immunity lasting several weeks , which can be given a second or third time, and with a historical track record of preventing other infections from entirely different RNA viruses (such as protecting against influenza). Therefore, it should be really helpful for some months, and I think get us past a second wave of SARS-CoV-2, and help people return to work safely. I don't understand delays or apparent lack of interest. Who can possibly be against this? If you hear of hypothetical problems we can show you that these are false. Just ask the questions, and we can give you the evidence.

However, no answer from you suggests no interest and must quickly make alternative pathways. I am though quite surprised and fear you are receiving "fake news" if you will pardon the expression. Some have been against this who defend their old and failed position on polio eradication with their promotion of the use of the inactivated polio virus vaccine. Please note that in the US between 1962 and 1985 we received (safely) the oral polio (OPV). Moreover, if vaccinated already there has not been a single case of a complication and BILLIONS have received it. No it will not last long as innate immunity is short lived, but we strongly believe that we can break the back of the SARS-CoVID-2 spread. Also note that this is what Bill Gates is doing now in India and much of the Eastern hemisphere.

There are countries outside the US wanting to move fast on this. We are waiting for your reply.

Robert Gallo
Director, Institute of Human Virology,
Professor of Medicine and Professor of Microbiology,
UMB, School of Medicine, Baltimore,

And
Co-founder and International Science Advisor of the Global Virus Network (GVN)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 12/14/2020 12:55:43 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Appell, Evan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
Subject: FW: ACTIV Leadership call
Flag: Follow up

Just fyi concerning our accomodations for Larry C for Wednesday's LT. Sounds like no change to schedule. David

From: Corey MD, Larry <(b) (6)>
Sent: Saturday, December 12, 2020 2:28 AM
To: Santos, Michael (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Cc: Minnich, Beth <(b) (6)> Appell, Evan <(b) (6)>
Subject: RE: ACTIV Leadership call

Appreciate it

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Friday, December 11, 2020 11:55 AM
To: Wholley, David (FNIH) [T] <(b) (6)> >; Corey MD, Larry <(b) (6)> >
Cc: Minnich, Beth <(b) (6)> >; Appell, Evan <(b) (6)>
Subject: RE: ACTIV Leadership call

Hi all,

It sounds like this will be easy to work out. If we schedule Vaccines 3rd, that discussion should begin around 8am PT / 11am ET, which will be well after the 7:30am PT scheduled end of UW Grand Rounds.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, December 11, 2020 2:37 PM
To: Corey MD, Larry <(b) (6)>
Cc: Minnich, Beth <(b) (6)> >; Santos, Michael (FNIH) [T] <(b) (6)> >; Appell, Evan

(b) (6)

Subject: RE: ACTIV Leadership call

Hi, Larry – we are scheduled to spend 75 minutes of our time, from 10:05 AM – 11:20AM, to hear from three working groups including Vaccines, with a 20 minute slot suggested for Vaccines. We can schedule that anytime (i.e., 1st, 2nd, 3rd) during the stated window to accommodate your grand rounds. Let us know what you'd like to do. Please copy Mike Santos and Evan Appel on your reply.

Regards,
David

From: Corey MD, Larry (b) (6)

Sent: Friday, December 11, 2020 2:16 PM

To: Wholley, David (FNIH) [T] (b) (6)

Cc: Minnich, Beth (b) (6)

Subject: ACTIV Leadership call

David

I have a potential conflict for the ACTIV leadership call on Dec 16. I am told there is a desire to discuss the Transmission / College trial on the call. I have been scheduled to give Grand Rounds to a medical group at UW for a couple months from 630 to 730 am PT. As the transmission trial is of more importance to me I wonder if it's possible to structure the ACTIV Leadership call for me to adhere to my commitment. So hence the email. If the transmission trial is not on the agenda .. ok

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 9:53:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [(b) (6)] Cavaleri, Marco [(b) (6)] Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6)] Culp, Michelle (NIH/OD) [E] [(b) (6)] Victoria Davey [(b) (6)] Disbrow, Gary (OS/ASPR/BARDA) [(b) (6)] Dolsten, Mikael [(b) (6)] Erbeling, Emily (NIH/NIAID) [E] [(b) (6)] Erck, Stan [(b) (6)] Gadbois, Ellen (NIH/OD) [E] [(b) (6)] Gibbons, Gary (NIH/NHLBI) [E] [(b) (6)] Hudson, Thomas [(b) (6)] James, Stephanie (FNIH) [T] [(b) (6)] Johnson, Robert (OS/ASPR/BARDA) [(b) (6)]; Kramer, Lynn [(b) (6)] Lane, Cliff (NIH/NIAID) [E] [(b) (6)] Mascola, John (NIH/VRC) [E] [(b) (6)] Meeker, David [(b) (6)] Menetski, Joseph (FNIH) [T] [(b) (6)] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6)] Pandya, Hitesh [(b) (6)]; Pao, William [(b) (6)] Parker, Ashley (NIH/OD) [E] [(b) (6)] Perlmutter, Roger [(b) (6)] Plenge, Robert [(b) (6)] Plump, Andy [(b) (6)] Reese, David [(b) (6)] Rouse, Doris [(b) (6)] Santos, Michael (FNIH) [T] [(b) (6)] Skovronsky, Daniel [(b) (6)] Stein, Peter (FDA/CDER) [(b) (6)] Stoffels, Paul [(b) (6)] Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Talley, Michael [(b) (6)] Tsai, John [(b) (6)] Vessey, Rupert [(b) (6)] Virgin, Skip [(b) (6)] Wholley, David (FNIH) [T] [(b) (6)] Woodcock, Janet (FDA/OC) [(b) (6)] Young, John [(b) (6)] Anderson, James (NIH/OD) [E] [(b) (6)]; Burklow, John (NIH/OD) [E] [(b) (6)] Carluccio, Dana [(b) (6)] Castillejos, Carlos [(b) (6)] FNIH Central Account [(b) (6)] Hallett, Adrienne (NIH/OD) [E] [(b) (6)] Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)] Myles, Renate (NIH/OD) [E] [(b) (6)] Wolinetz, Carrie (NIH/OD) [E] [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [(b) (6)] Desrosiers, Betsy [(b) (6)] Eric Hughes [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [(b) (6)] Lowy, Douglas (NCI) [(b) (6)] Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Meltzer, Abbey (FNIH) [T] [(b) (6)] Adam, Stacey (FNIH) [T] [(b) (6)] Margaret Anderson [(b) (6)] Appell, Evan [(b) (6)] Chen, Helen [(b) (6)]; Connelly, Sarah [(b) (6)] Gonzalez, Nina [(b) (6)] Hawk, Harrison [(b) (6)] Mendelson, Jesse [(b) (6)] Nasr, Hana [(b) (6)] Sorosa, Alex [(b) (6)] Stratton, Benjamin [(b) (6)] btolman [(b) (6)] Wachtel, Jonathan [(b) (6)]; Embry, Alan (NIH/NIAID) [E] [(b) (6)] Venkayya, Rajeev [(b) (6)] Bancel, Stephane [(b) (6)] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John [(b) (6)] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pangalos, Mene [(b) (6)] Paul, Steve [(b) (6)] Rachel Ramoni [(b) (6)] Reed, John [(b) (6)]
CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6)] Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)] Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)] Carver, Trea (NIH) [C] [(b) (6)] Caulfied, Anita [(b) (6)] Coan, Amanda [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6)].gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; Edl, Susan [(b) (6)] Fuhrer, Nicole [(b) (6)] Giorgi, Sara [(b) (6)] Hoban, Michelle [(b) (6)] Hoffstetter, Renata (FNIH) [T] [(b) (6)] Iberdemaj, Vaide [(b) (6)] Jenkins, Christine S. [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Lever, Susan [(b) (6)] Magbie-Robinson, Kim (NIH/OD) [C] [(b) (6)] Martin,

Melisa [(b) (6)] ; Minnich, Beth
 [(b) (6)] ; Perala, Mie [(b) (6)] ; Protasiewicz, Ann
 [ann. (b) (6)] ; Riccobene, Kim [(b) (6)] ; Riffin, Mary [(b) (6)]
 Ripley, Nadege [(b) (6)] ; Schuster, Donna [(b) (6)] ; Sepulveda,
 Dorina (FNIH) [T] [(b) (6)] ; Simon, Dina (NIH/OD) [C] [dina. (b) (6)] ; Suhana, Tina (NIH/VRC)
 [E] [(b) (6)] ; Thomas, Ashley (FDA/CDER) [(b) (6)] ; Wood, Gretchen (NIH/OD)
 [E] [(b) (6)] ; Hughes, Karen (NIH/OD) [E] [(b) (6)] ; Togashi, Mieko (NIH/NCI) [E]
 [(b) (6)] ; Underwood, Nancy [(b) (6)] ; Zottoli, Jessica
 [(b) (6)] ; Regan, Donna M [(b) (6)] ; Vessey, Rupert
 [(b) (6)] ; Burke, Leslie [(b) (6)] ; John Lepore [(b) (6)]
 Lowy, Douglas (NIH/NCI) [E] [(b) (6)] ; Grant, Sarah [(b) (6)] ; Pruitt, Kim
 (NIH/NLM/NCBI) [E] [(b) (6)] ; Sherry, Steve (NIH/NLM/NCBI) [E] [(b) (6)] ; Bell,
 Julie [(b) (6)]

Subject: *ACTIV Leadership Team Call #14

Attachments: 03.18.21 ACTIV EC and Leadership Team Meeting 20210317_vFinal.pdf; 03.18.21 ACTIV EC and Leadership Team Meeting APPENDIX_20210317_vF.pdf; 2021-02-17_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf

Location: https://fnih.zoom.us/ (b) (6)

Start: 3/18/2021 2:30:00 PM

End: 3/18/2021 4:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connolly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; (b) (6)

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Vessey, Rupert; Burke, Leslie; John Lepore; Lowy, Douglas (NIH/NCI) [E]; Grant, Sarah; Pruitt, Kim (NIH/NLM/NCBI) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]

Joseph Menetski is inviting you to a scheduled zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/22/2020 1:36:18 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]
Subject: ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5
Location: <https://fnih.zoom.> (b) (6)
Start: 4/30/2020 7:00:00 PM
End: 4/30/2020 8:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

Dear TX-Clinical APSG,

I had my days incorrect. This meeting was supposed to be tomorrow (Wednesday). I don't think this is the right timing, so I am moving it to Thursday and scheduling another call on Friday per our discussion.

Thanks,

Stacey

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/14/2020 2:36:51 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: JAMA Viewpoint on ACTIV: please review

yes

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 10:34 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: JAMA Viewpoint on ACTIV: please review

Has not gone out yet but I've placed everyone's email in the bcc line except for Renate, Abbey, and you. Figured FNIH would want to be looped in to those responses as well?

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Thursday, May 14, 2020 10:29 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: JAMA Viewpoint on ACTIV: please review

This was sent as a .bcc yes?

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Myles, Renate (NIH/OD) [E] <(b) (6)>; Kolberg, Rebecca (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

To:
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>
Bcc: Stoffels, Paul <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Pao, William <(b) (6)>; Woodcock, Janet (FDA/CDER) <(b) (6)>; Arvin, Ann <(b) (6)>; Buchbinder, Susan <(b) (6)>; Corey, Larry <(b) (6)>; Davis, Mark <(b) (6)>; Emini, Emilio <(b) (6)>; Hanon, Emmanuel <(b) (6)>; Haynes, Barton <(b) (6)>; Hotez, Peter <(b) (6)>; Jansen, Kathrin <(b) (6)>; Lanzavecchia, Antonio <(b) (6)>; Lowy, Douglas (NIH/NCI) [E] <(b) (6)>; Marks, Peter (FDA/CBER) <(b) (6)>; Mascola, John <(b) (6)>; Messonnier, Nancy

(CDC/DDID/NCIRD/OD) < (b) (6) Offit, Paul < (b) (6) Parker, Ashley (NIH/OD) [E]
 (b) (6) ; Santos, Michael (FNIH) [T] (b) (6) >; Santos, Nancy (b) (6) ;
 Schuitemaker, Hanneke (b) (6) ; Tartaglia, Jim (b) (6) Tolman, Brett
 < (b) (6) ; Zaks, Tal (b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6) >;
 Michael, Nelson, (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) ; Bascles, Lionel
 (b) (6) >; Cohen, Myron (b) (6) >; Corey, Larry (b) (6)
 Desrosiers, Betsy (b) (6) ; Dickens, Jim (NIH/NCATS) [C] (b) (6) >;
 Doroshov, James (NIH/NCI) [E] (b) (6) Goff, David (NIH/NHLBI) [E] (b) (6) Heaton,
 Penny (b) (6) >; Kurilla, Mike (b) (6) Nayak, Seema (NIH/NIAID) [E]
 (b) (6) ; Parker, Ashley (NIH/OD) [E] < (b) (6) Payton, Manzine
 (b) (6) >; Resnansky, Laura (b) (6) Srinivasan, Badhri
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) Karen (FNIH) [T]
 (b) (6) Vincent, Mike (b) (6) Wachtel, Jonathan (b) (6)
 Woodcock, Janet (FDA/CDER) (b) (6) > (b) (6) Sizemore, Christine
 (NIH/FIC) [E] (b) (6) Victoria Davey (b) (6) Qashu, Felicia (NIH/OD) [E]
 (b) (6) Weinmann, (b) (6) >; Mensah, (b) (6)
 Adam, Stacey (FNIH) [T] (b) (6) >; Bozzette, Sam (NIH/NCATS) [E] (b) (6) >; Buchman, Tim
 (OS/ASPR/BARDA) (CTR) < (b) (6) Butterton, Joan (b) (6) Currier, Judy
 (b) (6) De Claro, R. Angelo (FDA/CDER) (b) (6) Draghia-Akli, Ruxandra
 < (b) (6) ; Eisner, Mark (b) (6) >; Garner,
 Carlos < (b) (6) Gottesdiener, Keith < (b) (6) Hughes, Eric
 (b) (6) Kim, Elizabeth (b) (6) LaVange, Lisa (b) (6) ; Levy, Elliot
 (b) (6) >; Mellors, John (b) (6) ; Menon, Sandeep (b) (6) >; Parker,
 Ashley (NIH/OD) [E] < (b) (6) Patel, Naimish < (b) (6) Peppercorn, Amanda
 (b) (6) >; Poole, Mike < (b) (6) Proschan, Michael
 (b) (6) ; Read, Sarah (b) (6) ; Santos, Michael (FNIH) [T] (b) (6) Shen,
 Yuan Li (FDA/CDER) (b) (6) Stein, Peter (FDA/CDER) (b) (6)
 ≤ (b) (6) Koroshetz, Walter (b) (6) >; Farley, John (b) (6) >;
 (b) (6) Qashu, Felicia (b) (6) Burgess,
 Timothy (b) (6) Reineck, Lora (b) (6) >; Aggarwal, Neil (b) (6)

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.**

Thanks,
 Francis

Francis Collins, MD, PhD
 NIH Director

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 10/20/2020 5:16:51 PM
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(b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa];
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [dana. (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski (b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: ACTIV Preclinical full working group

Location: https://fnih.zoom.us (b) (6)

Start: 10/21/2020 2:15:00 PM

End: 10/21/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
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(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
Optional Attendees: (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher
(NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric;
Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen
(FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;
Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD)
[C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI)
[E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson,
James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/2/2020 2:45:51 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)]; Amanda Peppercorn [(b) (6)]; Breuer, Sebastian [(b) (6)]; Martin, Flavius [(b) (6)]; Andrew Charles Adams [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerl]; Smith, David [(b) (6)]; Jacqueline Kirchner [(b) (6)]
CC: [(b) (6)]; Chen, Helen Q. [(b) (6)]; Payton, Natalie [(b) (6)]; Andrew Para [(b) (6)]; [(b) (6)]; Dana Carluccio [(b) (6)]; Lucas Smalldon [(b) (6)]; Rose Li Central Account [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization - mAb Subteam Meeting
Attachments: ACTIV_TX-Clinical_mAb Sub Team Meeting Agenda_20200602.pdf; Gating Criteria for SARS CoV 2 mAbs moving into Phase II studies 052820.docx; ITPP COVID-19 mAb PREP PEP __Exec Summ.docx

Dear ACTIV Agent Prioritization – mAb Subteam,

Please find attached the materials for today's meeting, which is confirmed.

1. Meeting agenda
2. Current list of mAb Criteria generated by this team
3. A document shared with us by the Gates team about their considerations for mAb for prophylaxis

A representative from Gates will be joining us today, and if we have time at the end we can discuss there effort a bit. However, the main focus of this meeting will be to address the feedback that was shared with this team from the TX-Clinical Working Group from their meeting last week, which is mainly to reduce and refine the criteria to the minimal necessary mAb to enter a Phase 2 trial.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/22/2020 1:15:24 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan [(b) (6) Collins, Sylva (FDA/CDER) [(b) (6)]; Judy Currier [(b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) ; Read, Sarah (NIH/NIAID) [E] [(b) (6) Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Farley, John (FDA/CDER) [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Vincent, Michael [(b) (6)]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) ; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Stratton, Benjamin [(b) (6)]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #6 (Materials Attached)
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_23Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting #6 Agenda_04222020_v2.pdf; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 5_Key Takeaways_04222020.pdf
Location: <https://fnih.zoom.us> (b) (6)
Start: 4/23/2020 5:00:00 PM
End: 4/23/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US; Qashu, Felicia (NIH/OD) [E]; Stratton, Benjamin

Dear TX-Clinical Master Protocol subgroup,

Please find attached the materials for today's meeting.

1. Agenda
2. Slides with some updates of what we heard decided yesterday and what we need to focus on today. We may have a few other updates a little later.
3. The high level summary of yesterday's call again for your reference.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #5
Attachments: ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_04222020_v2.pdf; ACTIV Therapeutics-Clinical_MP Subgroup_24Apr2020 Meeting Guide_v1.pdf; BET synopsis v0.2 - 15Apr2020 DRAFT.pdf; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 4_Key Takeaways_04212020_v2.pdf
Location: https://fnih.zoom.us (b) (6)
Start: 4/22/2020 6:00:00 PM
End: 4/22/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear ACTIV TX-Clinical MP Subgroup,

Please find attached the materials for today's meeting.

1. Agenda
2. Slides from Yesterday, we will pick up where we left off. We have tried to update the de novo timelines accordingly.
3. BET Protocol that was sent yesterday
4. High Level Summary and Action Items from yesterday.

Thanks,
Stacey

Join Zoom Meeting

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Amanda Peppercorn [(b) (6)]
Sent: 5/14/2020 3:59:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, you may use my name.

Best,

Amanda

Amanda Peppercorn, M.D.
GSK Research & Development
mobile (b) (6)
email (b) (6)

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Myles, Renate (NIH/OD) [E] < (b) (6) > Meltzer, Abbey (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >
Subject: Time sensitive: Making your ACTIV Participation Public

EXTERNAL

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

COLL0000009500-2515352

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/19/2020 5:36:31 PM
To: Stephane Bancel [(b) (6)]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: URGENT: Invitation to join the ACTIV Vaccines Working Group
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

Dear Stephane,

As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course still no proven treatment or vaccine.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with you at Moderna on accelerated testing of a vaccine candidate. In order to broaden the response we announced on Thursday a new public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics, which we have decided to call Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development.

I have heard and very much appreciate your interest in ACTIV. If you are amenable I would like to ask you if you would be willing to join as **a member on the Vaccines Working Group** which is being co-chaired by Doug Lowy of NCI and Kathrin Jansen of Pfizer. This group is charged with establishing a collaborative framework for advancing vaccine development. They are having just their second meeting tomorrow morning, so I expect there will still be plenty of areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santos (b) (6) at FNIH, who will get to you immediately with the meeting logistics. I look forward to working with you on this critical effort.

Best,
Francis

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/11/2020 2:09:15 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: RE: slides from today and ACTIV Vaccine Committee
Flag: Follow up

Hi Francis,

I have a regularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (Monday) morning. If you can be free then and would like to join, that's an option. If that doesn't work, we can find another time before the Wednesday meeting (1pm).

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Sent: Sunday, May 10, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Subject: Re: slides from today and ACTIV Vaccine Committee

Francis
Despite the reassurance on the call today that the issues have been socialized with the WG, I recommend that we do have a separate discussion with them. We should do everything possible to make this transition as smoothly as possible.
Larry

From: Francis Collins (b) (6)
Date: Sunday, May 10, 2020 at 9:52 PM
To: "Wholley, David (FNIH) [T]" (b) (6), "Santos, Michael (FNIH) [T]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" (b) (6)
Subject: FW: slides from today and ACTIV Vaccine Committee

See slides and note from Larry Corey.

Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?

FC

From: Corey MD, Larry (b) (6)
Sent: Sunday, May 10, 2020 9:35 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: slides from today and ACTIV Vaccine Committee

Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements ; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of the harmonized design ; she voices the issue all Pharma companies have in a real viable market ; they don't want head to head comparisons ; parallel universes is how they always operate .

The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.

If there are other issues of concern just call My cell is (b) (6) .

Thanks Larry

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 3/2/2021 7:35:50 PM
To: (b) (6) [(b) (6)]
Subject: RE: [EXTERNAL] a few follow ups

Yes, we also delighted to push forward on the protease inhibitors!

And yes also to design of vaccines against B.1.351 and possible need for boosts. I'm just hoping there's not an even worse variant lurking out there. Come on people, get vaccinated!

Best, Francis

From: (b) (6) (b) (6)
Sent: Tuesday, March 2, 2021 9:52 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Subject: Re: [EXTERNAL] a few follow ups

Francis

I was thrilled to hear that ACTIV approved our IV and ORAL protease inhibitor (PI) pending phase 1 data on oral PI

Confidentially, we just dosed a handful of individuals w our oral PI drug this week and are progressing rapidly. Hope to soon have the data we need to start the P2/3 w ACTIV

Let's stay in touch

Anything to catch up on on the next steps w Covid vaccines. Seems like Moderna-NIH and Pfizer are running similar studies to assess third boost and variant vaccine etc

(b) (6)

Sent from my iPhone

On Feb 15, 2021, at 19:09, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Hi (b) (6)

Very interesting presentation, and a great opportunity to work together on the next steps. Let's do this!

Best, Francis

From: (b) (6) (b) (6)
Sent: Monday, February 15, 2021 3:34 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Dear Francis

COLL0000018651-2515355

Thanks for organizing that we all could come together today on a holiday to swiftly discuss the protease inhibitor program

We are very excited to progress the discussed partnership

Best

(b) (6)

Sent from my iPhone

On Feb 13, 2021, at 11:49, Collins, Francis (NIH/OD) [E](> wrote:

Though it's a federal holiday, Monday might also be a possibility – I'd be fine with that.

Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Saturday, February 13, 2021 11:17 AM

To: (b) (6) (b) (6)

Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Lane, Cliff (NIH/NIAID) [E]

(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Wood,

Gretchen (NIH/OD) [E] <(b) (6)>; Barasch, Kimberly (NIH/NIAID) [E]

(b) (6) Conrad, Patricia (NIH/NIAID) [E]

<(b) (6)>

Subject: RE: [EXTERNAL] a few follow ups

Hi (b) (6)

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

From: (b) (6) >

Sent: Friday, February 12, 2021 2:32 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group, I am pleased also to present the protease drug highlights myself and John together with our CEO Albert Bourla from Pfizer to meet the three of you

COLL0000018651-2515355

Best

(b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16, (b) (6)

(b) (6)

wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team . We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you , Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (Pi) drugs .

In this time of SARSCov2 viral evolution , they seems like a drug class w great promise .

We have submitted the IV PI drug to ACTIV w positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting w you. If you want to have some more detailed background science on the drugs , I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton . Liesa participated in ACTIV since the start within therapeutics related work streams .

Look forward to your response

Best

(b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E]

< (b) (6) wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all

coronaviruses is extremely encouraging – will this even cure the common cold? 😊 I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

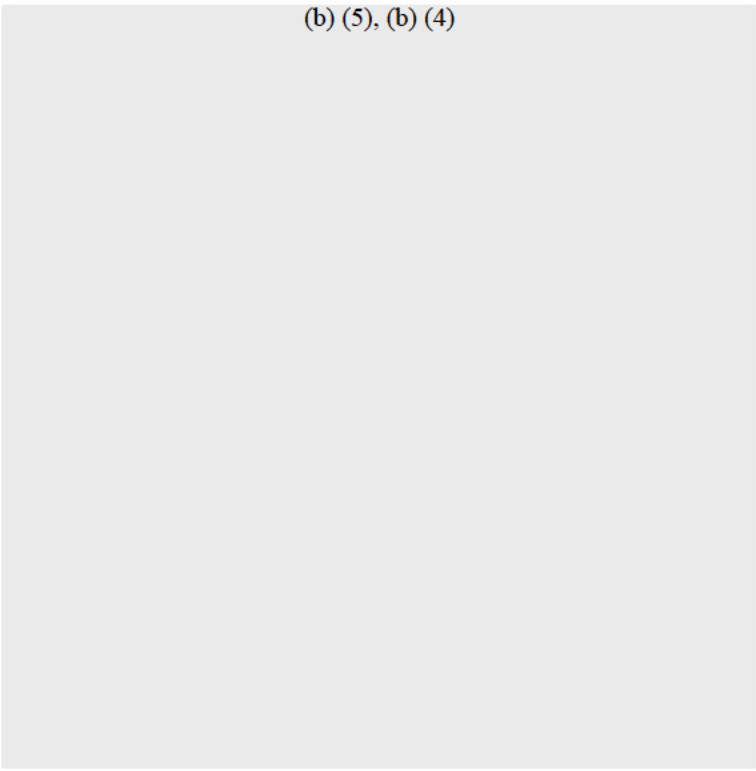
From: (b) (6) (b) (6)
Sent: Wednesday, February 10, 2021 8:36 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article but TIME paper was great

The exciting piece w the antiviral protease inhibitor (PI) drugs is that they are pan-corona virus active w potential as a drug for any new pandemic coronavirus. They also will inhibit all presently known SARSCov2 mutant variants that mainly affect SPIKE

(b) (5), (b) (4)



(b) (5), (b) (4)

(b) (6)

Sent from my iPhone

On Feb 10, 2021, at 06:33, Collins,
Francis (NIH/OD) [E]

(b) (6) wrote:

Hi (b) (6)

Just checking in. First, thanks for your kind words that were quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60

Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/17/2020 6:10:12 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: ChAdOx1
Flag: Follow up

How should we handle this? I think we agreed that calling out Kathrin at this point would likely not be productive. If this is a call to discuss getting Pfizer's vaccine on board, that is another matter. Thoughts?

From: Marks, Peter <(b) (6)>
Sent: Saturday, May 16, 2020 3:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>
Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

Best Regards,
Peter

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:12 AM
To: Marks, Peter <(b) (6)> >; Mascola, John R (NIH) <(b) (6)> >; Collins, Francis S (NIH) <(b) (6)> >; Lane, Henry C (NIH) <(b) (6)> >
Cc: Wholley, David N (NIH) <(b) (6)> >; Tabak, Lawrence A (NIH) <(b) (6)> >; Parker, Ashley S (NIH) <(b) (6)> >
Subject: RE: ChAdOx1

I would also like to be on that call with the Pfizer CEO if we could possible arrange it.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

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COLL0000016959-2515356

From: Marks, Peter (b) (6)
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] (b) (6); Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] (b) (6)
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] (b) (6)
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter <(b) (6)>; Collins, Francis S (NIH) (b) (6); Lane, Henry C (NIH) (b) (6)
Cc: Fauci, Anthony S (NIH) (b) (6); Wholley, David N (NIH) (b) (6); Tabak, Lawrence A (NIH) (b) (6); Parker, Ashley S (NIH) (b) (6)
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter (b) (6)
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Mascola, John (NIH/VRC) [E] <j (b) (6)> Lane, Cliff (NIH/NIAID) [E] (b) (6)
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6); Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)
(b) (5)

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, (b) (4), (b) (5)
(b) (4), (b) (5)

(b) (4), (b) (5) Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] (b) (6) >
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) (b) (6) >; Lane, Henry C (NIH) (b) (6) ; Marks, Peter <(b) (6)>
Cc: Fauci, Anthony S (NIH) (b) (6) Wholley, David N (NIH) <(b) (6)> ; Tabak, Lawrence A (NIH) (b) (6) >; Parker, Ashley S (NIH) (b) (6)
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/7/2021 8:08:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]
CC: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: URGENT: Need to Brief Secretary on COVID Therapeutics work TOMORROW!
Flag: Follow up

Sorry, my email was sent before I saw this—so you will need even fewer of the slides I sent!

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 7, 2021 3:49 PM
To: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> George, Jill (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Subject: RE: URGENT: Need to Brief Secretary on COVID Therapeutics work TOMORROW!

Just heard from Dawn that we will only have 20 minutes for the presentation and discussion. So this plan is going to need to be very much simplified. But please send me whatever ppts you have and I'll figure out how to put together a short and punchy deck.

FC

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 7, 2021 3:07 PM
To: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> George, Jill (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Subject: RE: URGENT: Need to Brief Secretary on COVID Therapeutics work TOMORROW!

Thanks, Cliff – and this is a great slide!

Francis

LTAB0000012644-2515358

From: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Sent: Wednesday, April 7, 2021 2:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> George, Jill (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Subject: Re: URGENT: Need to Brief Secretary on COVID Therapeutics work TOMORROW!

I might add the ACTT portfolio of studies (especially if highlighting remdesivir and baricitinib); the convalescent plasma studies and the immune IVIg studies.

One approach would be to talk about the portfolio of studies (by mechanisms as outlined below) followed by a summary of major findings thus far.

I have attached a slide I use to highlight the concept of different interventions at different times.

From: "Collins, Francis (NIH/OD) [E]" <(b) (6)>
Date: Wednesday, April 7, 2021 at 2:50 PM
To: "Parker, Ashley (NIH/OD) [E]" <(b) (6)> >, "George, Jill (NIH/OD) [E]" <(b) (6)> "Wholley, David (FNIH) [T]" <(b) (6)> "Adam, Stacey (FNIH) [T]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Embry, Alan (NIH/NIAID) [E]" <(b) (6)>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)> Lawrence Tabak <(b) (6)>
Subject: URGENT: Need to Brief Secretary on COVID Therapeutics work TOMORROW!

Hi Ashley, Jill, David, Stacey, Cliff, and Alan,

See thread below. OMG. Not much notice here! I'm still waiting to find out how much time we have for this. Keep in mind that Secy Becerra is a lawyer, not a scientist – this will need to be high level and avoid jargon.

I think the main points we will want to make are (though this may be too much if it turns out we only have 20 minutes):

- 1) Structure and function of NIH – this will be my first 1:1 with Becerra
- 2) Structure and function of the ACTIV partnership
- 3) Advances that have been achieved so far – maybe a table that shows where they are most useful (outpatient vs inpatient):
 - a. Antivirals – remdesivir
 - b. Immunomodulators – dexamethasone, baricitinib
 - c. Anticoagulants – full dose heparin in hosp'd patients not yet with organ failure
 - d. Monoclonal antibodies – single agent vs. cocktail
- 4) Drugs currently under investigation – include ACTIV-6 plans
- 5) Building momentum on small molecule antivirals
 - a. Pfizer IV and po agents
 - b. Merck/Ridgeback EIDD-2801 -- expect trial results soon?
 - c. New \$3.1B NIAID/NCATS/ORIP/BARDA program funded by ARP

For all of you – what slides do we already have that can be slotted in here? I'd really appreciate help!

Francis

From: O'Connell, Dawn (HHS/IOS) < (b) (6) >
Sent: Wednesday, April 7, 2021 1:56 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) >
Subject: RE: Brief Secretary on Therapeutics work

Great! A PPT that you can share at the time of the briefing would be great. I usually spend the first 10 minutes going over numbers and trends (you can jump in with me on this tomorrow) and then you can have the remaining time to walk through the work you've been doing. I'll ask the scheduling team to add you and Larry now.

Thanks Francis!

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, April 7, 2021 1:54 PM
To: O'Connell, Dawn (HHS/IOS) < (b) (6) >
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) >
Subject: RE: Brief Secretary on Therapeutics work

Certainly! I'd like Larry to join too. What should we put together for materials, and when are those needed?

Francis

From: O'Connell, Dawn (HHS/IOS) < (b) (6) >
Sent: Wednesday, April 7, 2021 1:44 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) >
Subject: Brief Secretary on Therapeutics work

Francis, I was wondering if you would be available tomorrow at 10am to join a Daily COVID check in I do with the Secretary in order to update him on all of the work NIH has been doing on therapeutics. Would you be available?

Dawn O'Connell
Senior Counselor to the Secretary
HHS COVID-19 Response
(b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/27/2020 1:20:05 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6)]; Kim, Elizabeth [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wachtel, Jonathan (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tolman, Brett [(b) (6) Alvarez, Rosa Maria [(b) (6) Chen, Helen Q. [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: COVID-19 Status Reports and Dashboards from VA and UC System

Attachments: Copy of DailyReport_20200522.xlsx; UC Report 5-22-20.pdf

Dear ACTIV TX-Clinical Working Group,

Please find attached some initial RWD that the FDA team has been kind enough to give us access to and will update for our group each week if we would find it useful.

Please let me know if either our Agent Prioritization Subgroup or the Master Protocol Subgroup would find this data useful as we are prioritizing agents and planning trials. If so, I will work with Peter Stein to ensure our group gets the updated information at the proper cadence.

Please do not share beyond the ACTIV group at this time.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Stein, Peter <(b) (6)>
Sent: Monday, May 25, 2020 6:59 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: reports

Stacey,
Amy Abernathy is coordinating a group pulling in RWD from a number of sources – with daily reports from the VA and UC system. She has permission to have these shared with the ACTIV group – so I’ve attached reports from last week, and if useful, we can have these at whatever frequency we prefer.

Regards, Peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 4/27/2020 7:58:41 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Kim, Elizabeth [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(b) (6)

CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Protasiewicz, Ann [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; FNIH Central Account [(b) (6) Li, Rose [(b) (6) Zottoli, Jessica (b) (6)

Subject: ACTIV Response Partnership Leadership Team Meeting #4

Location: <https://fnih.zoom.us/j> (b) (6)

Start: 5/20/2020 7:30:00 PM

End: 5/20/2020 9:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/1/2020 1:21:51 AM
To: Heatherington, Anne [(b) (6)]; Plump, Andrew [(b) (6)]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: Data Sharing Slide for ACTIV LT Meeting

Yes, I suppose Andy or Francis can talk to that if needed. Thanks for reminding us.

From: Heatherington, Anne < (b) (6) >
Sent: Tuesday, June 30, 2020 8:55 PM
To: Plump, Andrew < (b) (6) >
Cc: Wholley, David (FNIH) [T] < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >
Subject: Re: Data Sharing Slide for ACTIV LT Meeting

Thanks David. One additional point to note is that we now have clearly assigned points of contact between COVID R&D (Sandeep Menon, Pfizer) and NIH (Michelle Culp) to ensure a smooth relationship.
Anne

On Jun 30, 2020, at 7:34 PM, Plump, Andrew < (b) (6) > wrote:

Hi David - Yes, I will be at tomorrow's meeting and can speak to these points together with Francis.

Cheers,
Andy

Sent from my iPad

On Jun 30, 2020, at 7:33 PM, Wholley, David (FNIH) [T] < (b) (6) > wrote:

Be advised that this email came from outside Takeda / お知らせ：社外から送信されたメールです

Hi Andy—

Just a heads up that on tomorrow's Leadership Team call (which I see you have accepted on your calendar) we will be addressing as an action item the follow up on data sharing discussions. We've prepared the following reasonably high level slide that you and Francis could talk to. Thanks, David

<Update on Data Sharing_Slide for ACTIV LT Meeting.pptx>

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Sent: 4/15/2020 9:27:47 PM

To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
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 Arvin, Ann [(b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) Haynes, Barton [(b) (6)
 (b) (6) (b) (6) Marks, Peter (FDA/CBER) (b) (6)]; Mascola, John
 (NIH/VRC) [E] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Offit, Paul
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 (b) (6) Tal Zaks [(b) (6) (b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Kozlowski, Mary (NIH/NCI) [C]
 [(b) (6) Johnson, Maureen (NIH/NCI) [E] [(b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
 (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6)
 Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E]
 [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
 (b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] (b) (6)
 James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)
 Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael
 (NIH/NCATS) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John
 [john. (b) (6) Gonzalez, Nina [(b) (6) (b) (6)
 (b) (6) Wachtel, Jonathan (b) (6) Arvin, Ann
 [(b) (6) Anderson, Margaret [(b) (6) Marston, Hilary (NIH/NIAID) [E]
 (b) (6)]; Bethany Stokes (b) (6)]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.com/nih/> (b) (6)

Start: 4/20/2020 1:00:00 PM

End: 4/20/2020 2:00:00 PM

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 (b) (6) Haynes, Barton; (b) (6)
 (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy
 (CDC/DDID/NCIRD/OD); Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA);
 (b) (6) Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E];
 (b) (6) (b) (6) (b) (6) (b) (6)
 Austin, Sarah (NIH/NIAID) [E]; (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis
 (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey
 (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers,
 Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Gonzalez, Nina;
 (b) (6) (b) (6) Wachtel, Jonathan; Ann Arvin; Anderson,
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Sent: 6/1/2020 4:48:17 AM
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 Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Benjamin [(b) (6)] Anderson, Margaret [(b) (6)]

Subject: Notes from the ACTIV Vaccines Working Group meeting

Attachments: 2020-05-28 Vaccines Working Group meeting Summary Notes.docx; ACTIV_Presentation_MBiggerstaff.pdf

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in the last meeting of the Vaccines Working Group. Attached are the notes from that meeting and the slides that Matt Biggerstaff presented.

Please let us know if you have any questions or suggestions. We look forward to engaging with you in this week's meetings.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, May 27, 2020 1:12 PM
Subject: Agenda for ACTIV Vaccines Working Group meeting: Tomorrow, 28 May

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

The agenda for **Vaccines Working Group meeting** tomorrow (Thursday) at 2pm ET (11am PT / 8pm CEST) is:

- Matt Biggerstaff, from CDC's modeling team, will present on predictive modeling of incidence to inform vaccine efficacy trials
- Time permitting, we will discuss updates from the Sub-Groups

Given the importance of the first agenda item to the Vaccines Clinical Trials Sub-Group, we are inviting that group to join the meeting. The calendar invite follows this note. As a reminder, we have two meetings scheduled tomorrow, and many of you will also receive an email about the Vaccines Clinical Trials Sub-Group meeting (at 11am ET).

We also want to provide a preview of a coming set of requests: As we have previously discussed, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. The Vaccines Clinical Trials Sub-Group was asked for DSMB member recommendations: thanks to those who sent input. We will be sharing a list of potential DSMB members from NIAID with the Vaccines Clinical Trials Sub-Group (cc'ing the Working Group) today for feedback. Based on that feedback, NIAID will propose a list of members and alternates. We will circulate that list to the Vaccines Working Group (cc'ing the Sub-Group) for final input before NIAID finalizes the list and reaches out to proposed members. We apologize in advance for the short turn-around times that will be requested given the necessity of finalizing the DSMB members in time for an early July trial start.

We're looking forward to the meeting tomorrow. Please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [(b) (6)]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [(b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) | (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [(b) (6)]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [(b) (6) Charette, Marc (NIH/NHLBI) [E] [(b) (6) Fessel, Josh (NIH/NHLBI) [E] (b) (6)]; (b) (6) **CC:** Wholley, David (FNIH) [T] (b) (6)]; Austin, Christopher (NIH/NCATS) [E] [(b) (6) Melencio, Cheryl (FNIH) [T] [cmelencio@fni.org]; Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [michael. (b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes (b) (6) ; Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [dana. (b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Rodriguez, Robin D (b) (6) ; Dave Frankowski (b) (6) Baric, Toni C (b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Florence, Clint (NIH/NIAID) [E] [(b) (6) Nancy Haigwood [ha (b) (6) Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]

Start: 7/8/2020 2:00:00 PM

End: 7/8/2020 3:00:00 PM

Recurrence: (none)

Sent: 9/9/2020 9:11:44 PM
To: Chen, Helen Q. [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,

The hover over doesn't work in the PDF document but this will work when you display in presentation mode during the meeting tomorrow (agents in the hover over are those listed on CT.gov).

We (OD) will work with a developer when this goes live on the ACTIV website to ensure the feature will work.

-----Original Message-----

From: Chen, Helen Q. < (b) (6) >
Sent: Wednesday, September 9, 2020 4:11 PM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Appell, Evan < (b) (6) >
Subject: FW: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,

Please see below a question from Neil. My understanding is it will be a feature once it's live on the website - is that correct? Please feel free to provide any additional information / clarification that would help address Neil's inquiry. Thank you!

Warm regards,
Helen

-----Original Message-----

From: Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) >
Sent: Wednesday, September 9, 2020 4:07 PM
To: Chen, Helen Q. < (b) (6) >
Subject: [EXT] RE: ACTIV Therapeutics-Clinical Working Group Meeting

Thanks Helen. This has the potentially to be a really useful document. At this point, should we be able to see agent information if we hover over the black circle with an A in it? If so, that feature does not seem to be working (at least not for me).

Best,
Neil

Neil Aggarwal, MD
Chief, Lung Biology and Disease Branch
Division of Lung Diseases / NHLBI / NIH

-----Original Message-----

From: Chen, Helen Q. < (b) (6) >
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) > Bozzette, Sam (NIH/NCATS) [E] <sam.bozzette@nih.gov>;
Butterton, Joan < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) >
Drachia-Akli, Ruxandra < (b) (6) > Eisner, Mark < (b) (6) > Gottesdiener, Keith < (b) (6) >
< (b) (6) > Eric Hughes < (b) (6) > Judy Currier < (b) (6) >
> Kim, Elizabeth < (b) (6) > > LaVange, Lisa < (b) (6) > >;
Levy, Elliot < (b) (6) > Mellors, John W < (b) (6) > Menon, Sandeep < (b) (6) >
< (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Patel, Naimish < (b) (6) >
< (b) (6) > Peppercorn, Amanda < (b) (6) > Poole, Mike < (b) (6) >
< (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah < (b) (6) >
(NIH/NIAID) [E] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Shen, Yuan Li < (b) (6) >
(FDA/CDER) < (b) (6) > ; Stein, Peter (FDA/CDER) < (b) (6) > ; Wholley, David < (b) (6) >
(FNIH) [T] < (b) (6) > > Buchman, Tim (OS/ASPR/BARDA) (CTR) <Tim.Buchman@hhs.gov>; Collins, Sylvia < (b) (6) >
(FDA/CDER) < (b) (6) > > Amanda Peppercorn <amanda. (b) (6) > Garner, Carl < (b) (6) >
< (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Koroshetz, Walter < (b) (6) >
(NIH/NINDS) [E] < (b) (6) > .gov>; Timothy Burgess <timothy. (b) (6) > Reineck, Lora < (b) (6) >

(NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6)
 Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]
 < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner
 < (b) (6) Beigel, John (NIH) [E] < (b) (6) Phillips, L
 Revell CIV DTRA RD (USA) < (b) (6) >; Petrovick, Martha - 0449 - MITLL
 < (b) (6) Sizemore, Christine (NIH/FIC) [E]
 < (b) (6)
 CC: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy
 < (b) (6) >; Jansen, Kathrin < (b) (6) Kurilla, Michael
 (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John
 < (b) (6) Biggs, Mary < (b) (6) Butcher, Tina < (b) (6)
 Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T]
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]
 < (b) (6) Wachtel, Jonathan < (b) (6) Tolman < (b) (6) Alvarez,
 Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio
 < (b) (6) Rose Li Central Account < (b) (6) Margaret
 Anderson < (b) (6) Lucas Smalldon < (b) (6) Stratton,
 Benjamin < (b) (6) Mollica, Linda /US
 < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Patterson, Amy
 (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Marston,
 Hilary (NIH/NIAID) [E] < (b) (6) Wung, Peter /US < (b) (6) : Hoots, W. Keith
 (NIH/NHLBI) [E] < (b) (6) Groesch, Mary (NIH/NHLBI) [E] < (b) (6) Shipp,
 Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
 < (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6)
 Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Freire, Maria (FNIH)
 [T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)
 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
 Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6)
 Sent: Wednesday, June 17, 2020 8:48 AM
 To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
 CC: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
 Subject: ACTIV Therapeutics-Clinical Working Group Meeting
 When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
 Where: <https://secure-web.cisco> (b) (6)

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To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)

(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Isis. (b) (6)

CC: (b) (6) (b) (6) (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Diamond, Michael
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 (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];
 Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 (b) (6); Dave Frankowski (b) (6) Baric, Toni C
 (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
 (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 (b) (6) Mason, Stephen (b) (6) Connelly, Sarah (b) (6)
 (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
 (b) (6) Gonzalez, Nina (b) (6)

Start: 12/18/2020 1:00:00 PM

End: 12/18/2020 2:00:00 PM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) .gov; (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) Parker,
 Ashley (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu,
 Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello
 (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
 (b) (6)

Optional Attendees: (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher
 (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric;
 Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen
 (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;
 Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
 Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD)
 [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI)
 [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson,
 James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; (b) (6); Lumsden, Joanne
 (NIH/NCATS) [C]; K C Kent Lloyd

Sent: 3/3/2021 2:02:19 PM
To: (b) (6) [(b) (6)]
Subject: RE: [EXTERNAL] a few follow ups

Hi (b) (6)

I was just on a "war room" call with the ACTIV team and found I was confused about the plans for the IV and oral protease. I was under the impression that the IV agent would be ready to go imminently into ACTIV-3 – but the team seemed to indicate that the phase 1 trial wasn't completed yet. I was surprised, and thought there might have been confusion with the oral agent, which I know is doing through SAD and MAD right now. Can you clarify? We are ready to put the IV agent into an arm of ACTIV-3 right away, and would love to get started with that.

From: (b) (6) < (b) (6) >
Sent: Tuesday, March 2, 2021 2:55 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Subject: Re: [EXTERNAL] a few follow ups

All good then
Let's consider to catch up 1/1 in a couple of weeks or when you find it helpful on the many topics
Mikael

Sent from my iPhone

On Mar 2, 2021, at 14:36, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Yes, we also delighted to push forward on the protease inhibitors!

And yes also to design of vaccines against B.1.351 and possible need for boosts. I'm just hoping there's not an even worse variant lurking out there. Come on people, get vaccinated!

Best, Francis

From: (b) (6) (b) (6)
Sent: Tuesday, March 2, 2021 9:52 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Francis

I was thrilled to hear that ACTIV approved our IV and ORAL protease inhibitor (PI) pending phase 1 data on oral PI

Confidentially, we just dosed a handful of individuals w our oral PI drug this week and are progressing rapidly. Hope to soon have the data we need to start the P2/3 w ACTIV

Let's stay in touch

Anything to catch up on on the next steps w Covid vaccines . Seems like Moderna-NIH and Pfizer are running similar studies to assess third boost and variant vaccine etc

(b) (6)

Sent from my iPhone

On Feb 15, 2021, at 19:09, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Hi (b) (6)

Very interesting presentation, and a great opportunity to work together on the next steps. Let's do this!

Best, Francis

From: (b) (6) (b) (6)
Sent: Monday, February 15, 2021 3:34 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Dear Francis

Thanks for organizing that we all could come together today on a holiday to swiftly discuss the protease inhibitor program

We are very excited to progress the discussed partnership

Best

(b) (6)

Sent from my iPhone

On Feb 13, 2021, at 11:49, Collins, Francis (NIH/OD) [E]
< (b) (6) > wrote:

Though it's a federal holiday, Monday might also be a possibility – I'd be fine with that.

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, February 13, 2021 11:17 AM
To: (b) (6) <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Wholley, David (FNIH) [T] <(b) (6)>; Wood, Gretchen (NIH/OD) [E] <(b) (6)>; Barasch, Kimberly (NIH/NIAID) [E] (b) (6) >; Conrad, Patricia (NIH/NIAID) [E] (b) (6)
Subject: RE: [EXTERNAL] a few follow ups

Hi (b) (6)

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

From: (b) (6) (b) (6) >
Sent: Friday, February 12, 2021 2:32 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group, I am pleased also to present the protease drug highlights myself and John together with our CEO Albert Bourla from Pfizer to meet the three of you

Best
(b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16, (b) (6) wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team. We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you , Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (Pi) drugs .

In this time of SARSCov2 viral evolution , they seems like a drug class w great promise .

We have submitted the IV PI drug to ACTIV w positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting w you. If you want to have some more detailed background science on the drugs , I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton . Liesa participated in ACTIV since the start within therapeutics related work streams .

Look forward to your response

Best

(b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E]

(b) (6) wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? 😊 I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

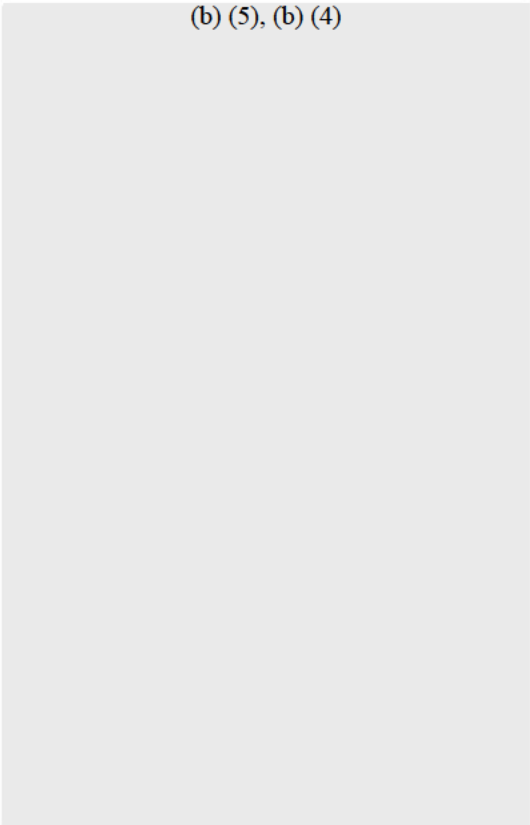
From: (b) (6)
(b) (6)
Sent: Wednesday, February 10, 2021
8:36 AM
To: Collins, Francis (NIH/OD) [E]
(b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

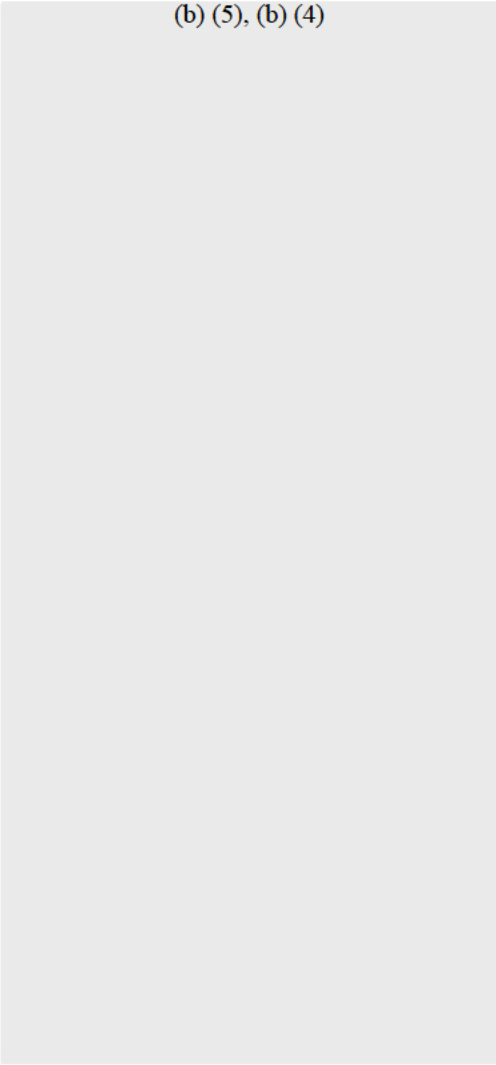
Good that you try to correct NYT article but TIME paper was great

The exciting piece w the antiviral protease inhibitor (PI) drugs is that they are pan-corona virus active w potential as a drug for any new pandemic coronavirus. They also will inhibit all presently known SARSCov2 mutant variants that mainly affect SPIKE

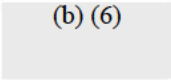
(b) (5), (b) (4)



(b) (5), (b) (4)



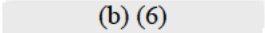
(b) (6)



Sent from my iPhone

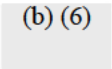
On Feb 10, 2021, at
06:33, Collins, Francis
(NIH/OD) [E]

(b) (6)



wrote:

Hi (b) (6)



Just checking in. First,
thanks for your kind
words that were

COLL0000012188-2515367

quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you

can tell me about
progress there?

All the best, Francis

From: Prabha Fernandes (b) (6)
Sent: 4/19/2020 3:19:48 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; 'Alvarez, Rosa Maria' [(b) (6)]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; 'Desrosiers, Betsy' [(b) (6) 'Hughes, Eric' [(b) (6) 'Jansen, Kathrin' (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Kim, Elizabeth' [(b) (6) 'Tolman, Brett' [(b) (6) 'Wachtel, Jonathan' (b) (6) 'Prabhavathi Fernandes' [(b) (6) 'Diamond, Michael' [(b) (6) 'Rose Li' [(b) (6) 'Dana Carluccio' (b) (6) ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]
Subject: RE: COVID Preclinical Working group Meeting #2
Attachments: Prabha Response to Friday 18th meeting action items.docx; 2020-04-17 ACTIV Preclinical TC Summary f2 Prabha.docx
Flag: Follow up

Good morning Joe,
Thank you for completing the Minutes!
I marked some comments. On the Action items, I have made a couple of comments.
I look forward to discussions tomorrow.
Best regards,
Prabha

-----Original Message-----

From: Menetski, Joseph (FNIH) [T] (b) (6)]>
Sent: Friday, April 17, 2020 10:41 PM
To: Menetski, Joseph (FNIH) [T] (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph < (b) (6) >
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]
< (b) (6) > Colvis, Christine (NIH/NCATS) [E]
< (b) (6) > Hewitt, Judith (NIH/NIAID) [E]
< (b) (6) > Deming, Damon (FDA/CDER)
< (b) (6) > (b) (6) (b) (6)
< (b) (6) > Parker, Ashley (NIH/OD) [E]
< (b) (6) > (b) (6) Adams, Peter
(OS/ASPR/BARDA) (b) (6) Jonson, Samantha (NIH/NCATS) [E]
< (b) (6) > Alvarez, Rosa Maria < (b) (6) >
Cc: Collins, Francis (NIH/OD) [E] < (b) (6) > Wholley, David
(FNIH) [T] < (b) (6) > Austin, Christopher (NIH/NCATS) [E]
(b) (6) Melencio, Cheryl (FNIH) [T] (b) (6)]>;
Desrosiers, Betsy < (b) (6) > Hughes, Eric
< (b) (6) > Jansen, Kathrin (b) (6)
Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Lowy, Douglas
(NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) >
Tountas, Karen (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T]
< (b) (6) > Adam, Stacey (FNIH) [T] (b) (6)]>; James,
Stephanie (FNIH) [T] < (b) (6) > Kim, Elizabeth (b) (6)]>;
Tolman, Brett < (b) (6) > Wachtel, Jonathan
< (b) (6) > Prabhavathi Fernandes
(b) (6) Diamond, Michael < (b) (6) > Rose
Li (b) (6)]>; Dana Carluccio
< (b) (6) > (b) (6) Lagos, Enrique (NIH/NCATS) [E]
< (b) (6) >
Subject: RE: COVID Preclinical Working group Meeting #2

Hi all,

Thank you again for taking the time to attend our meeting today. Please find attached the notes from the meeting.

At your earliest convenience, please send us your feedback on the data categories that we have laid out in the attached excel sheet (also included in the slides). If you have any that you would like to modify, add or remove - please let us know.

Also, this weekend we will be creating a basecamp site to store all the documents that we've shared so far. Please be on the lookout for an email inviting you to join this site.

Sincerely,

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Sunday, April 12, 2020 12:50 PM
To: Menetski, Joseph (FNIH) [T]: (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph; (b) (6) Ottinger,
Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith
(NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6)
(b) (6) Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Jonson,
Samantha (NIH/NCATS) [E]
Cc: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin,
Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;
Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy,
Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T];
Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)
[T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;

Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]
Subject: COVID Preclinical Working group Meeting #2
When: Friday, April 17, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://zoom.us/> (b) (6)

Saving time on the calendar.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
<https://zoom.us/j/> (b) (6)
<<https://zoom.us/j/> (b) (6)

Meeting ID: (b) (6)
Password: (b) (6)
One tap mobile
(b) (6) US (Chicago)
US (New York)

Dial by your location
(b) (6) US (Chicago)
US (New York)
US (San Jose)
US (San Jose)
US
US
US (Houston)

Meeting ID: (b) (6)
Password: (b) (6)
Find your local number: <https://zoom.us/u/> (b) (6)
<<https://zoom.us/u/> (b) (6)

From: Fauci, Anthony (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF38103D75134F658AE2D356F0396B94-AFAUCI]
Sent: 7/3/2020 4:15:15 PM
To: Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Gallo and OPV
Flag: Follow up

Doug:

There are several people with whom you could discuss this: Barney Graham (VRC/NIAID), Paul Offit (University of Pennsylvania), Richard Whitley (UAB), Larry Corey, Cliff lane, among others.

Best,
Tony

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Friday, July 3, 2020 12:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)>
Subject: Re: Gallo and OPV

Thanks, Tony. Can you suggest one or two people with whom I can discuss the issue? Doug

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>
Date: Friday, July 3, 2020 at 12:07 PM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)>, "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>, "Mascola, John (NIH/VRC) [E]" <(b) (6)>
Cc: "Wholley, David (FNIH) [T]" <(b) (6)>
Subject: RE: Gallo and OPV

This issue will not go away and so perhaps it is best to have the ACTIV Vaccines WG take a look at this and make some sort of recommendation.

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Friday, July 3, 2020 11:54 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)>
Subject: Re: Gallo and OPV

Hi Francis: The vaccine working group has not discussed this topic. Doug

From: "Collins, Francis (NIH/OD) [E]" (b) (6)
Date: Friday, July 3, 2020 at 11:46 AM
To: "Fauci, Anthony (NIH/NIAID) [E]" (b) (6), "Lane, Cliff (NIH/NIAID) [E]" (b) (6), "Lowy, Douglas (NIH/NCI) [E]" (b) (6), "Mascola, John (NIH/VRC) [E]" (b) (6)
>
Cc: "Wholley, David (FNIH) [T]" (b) (6)
Subject: RE: Gallo and OPV

Hi Tony, Cliff, Doug, and John (and looping in David)

Bob Gallo is back with a complaint that no one has followed up on the OPV idea. See attached. Was this discussed in the ACTIV Vaccines WG or in any other venue?

Tx, Francis

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Sent: Sunday, May 3, 2020 1:45 PM
To: Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Lowy, Douglas (NIH/NCI) [E] (b) (6); Mascola, John (NIH/VRC) [E] (b) (6) >
Subject: RE: Gallo and OPV

Totally agree with Cliff's advice.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

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From: Lane, Cliff (NIH/NIAID) [E] (b) (6)
Sent: Sunday, May 3, 2020 1:22 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Cc: Lowy, Douglas (NIH/NCI) [E] (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Mascola, John (NIH/VRC) [E] (b) (6)
Subject: Re: Gallo and OPV

Francis,

I am not sure you need any sort of detailed response. I would just send a thank-you and indicate you will be sure those working on this at NIH are aware.

Cliff

On May 3, 2020, at 12:55 PM, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Hi all,

I'm a bit at a loss to know how to respond to Bob Gallo. The aggressive manner in which he is promoting OPV causes me to worry he has lost objectivity about its promise. But is there any chance he has something here that could work?

Francis

From: Gallo, Robert (b) (6) >
Sent: Sunday, May 3, 2020 12:07 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Subject: RE: Your query to Dr. Kadlec

Dear Francis,

It was a pleasure to hear from you, and yes, it has been a long time since we met or even spoke. Moons ago I was set to write to you after reading your wonderful book, but I ended up instead speaking with others about it. I should add at this point that I did not quickly respond to your email of a few days ago because I simply missed it.

It is true that I strongly suggest that OPV be quickly (already it is not quickly) brought forward for induction of a strong innate immune response to prevent or markedly reduce SARS-CoV-2 infection and/or severity until the field obtains a proven safe and efficacious vaccine producing a long lasting, adaptive immunity. OPV is very safe (notably for OPV 1 and 3 as bOPV which we will use and completely safe in a vaccinated population), simple, cheap, rather obvious, yet unique among the massive number of vaccines many (maybe most) of which are the same or at least if not exactly the same aiming at the same mechanism (targeting the spike and searching for the putative correlate of neutralizing Abs.).

OPV should work for a few months and possibly longer. Also it should be working multiple times so I think could cover more than a few months, giving us time for a proven vaccine of adaptive immunity, which might be very long lasting as is hoped.

In the main the WHO comments are correct. Of course we sought and have letters of support from them as well as from many others. Though they are again supportive in their notes to you, there is one item that surprises me. They add that there was no clinical efficacy results as yet. They know or certainly should know that there is plenty of clinical data for this concept with BCG, OPV, and live Measles vaccine. Needless to say this is what turned me on during our regular Global Virus Network (GVN) conference calls. (Incidentally GVN is an organization I have thought of bringing to your attention. I think you would find it impressive and useful). I would be happy to share with you the clinical observations with OPV if you wish.

I would like to take a small diversion, but I suspect you are aware of these things. My colleagues and I respect the WHO because of its representation and because we have colleagues/friends there as well. However, sometimes bureaucracy of a massive degree leads to inaction or even much worse-- political expediency. I won't bother you with details of these unless you ask, but I had such experiences with HTLV-1 which we discovered in 1980 as the 1st human retrovirus and which cause not only the highest incidence of cancer (% of infections) of any virus and other fatal diseases as well but mainly in less developed countries (plus Japan) and again with HIV in 1984. Behavior was not beneficial. Perhaps it will be of relevance in the future because a few at WHO took a position to remove OPV (Sabin) in favor of IPV (Salk) in their polio eradication scheme. It was a huge failure. As my FDA collaborator, Konstantin Chumakov, says "Blessed be Bill Gates" because he saved OPV and saved the day and in so doing has produced a still better OPV.

There is indeed data also for BCG as well as live Measles though I know less of the latter. BCG is less available, requires injection, harder to make, not as safe, and we think unlikely to be as effective as OPV. Nonetheless, we favor its use too. The mechanisms will be similar.

You asked whether monkey trials are planned. For several reasons definitely not --though we are planning some monkey experiments, but not large enough for "clinical" conclusions. The main reasons are: 1) cost; 2) that billions not thousands or millions have received OPV safely and in our collective view (and we know the studies pretty well) protection has been clinically shown; 3) In a pandemic we wished to move quickly (so far we must say that has not been achieved). A typical monkey vaccine study will take time, but 4) in this case it would be a huge amount of lost time as monkeys require great doses of polio for infection and monkeys have to be trained to drink their orange juice. It would be hard to imagine that such studies would even give us useful information.

On a final digression Francis I have had 36 years of on/off experiences with glycosylated spike proteins--their analyses immunologically and especially regarding use in vaccines and developing neutralizing Abs. I believe it will be a mistake to put most eggs in that basket. The risks: shortened antibody half life; 2) protection NOT correlating with neutralizing Abs; 3) sometimes hazards from them. Admittedly, they might work, but I trust and hope that not everything is going in this bag. If you wish to discuss this again I will be available.

Finally, I had no idea you were into vaccines or SARS-2 nor any part of CoVID-19 disease, but I am very happy to learn this.

Thanks.

Bob Gallo

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, April 30, 2020 5:00 PM
To: Gallo, Robert <(b) (6)>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Kadlec, Robert (OS/ASPR/IO) (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) (b) (6); Johnson, Robert (OS/ASPR/BARDA) <(b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Subject: Your query to Dr. Kadlec

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Dear Bob,

It's been quite a while since we've chatted. Bob Kadlec asked me to respond to your query about the possible use of OPV to activate innate immunity and provide COVID-19 protection. Has this been tested in a non-human primate model? I note the recommendation below that says a clinical trial is planned – can you tell me more about that?

As you can imagine, we are all flat out on the vaccine development pathway!

Francis

The use of oral polio vaccine (OPV) to prevent SARS-CoV2 (Polio Eradication Campaign)

There is no evidence that oral poliovirus vaccine (OPV) protects people against infection with COVID-19 virus.

A clinical trial addressing this question is planned in the USA, and WHO will evaluate the evidence when it is available.

In the absence of evidence, WHO does not recommend OPV vaccination for the prevention of COVID-19. WHO continues to recommend OPV as part of essential immunization services to prevent poliomyelitis and as part of global polio eradication efforts.

There are experimental signals from various studies over the years that OPV has non-specific effects on the immune system. These effects have not been well characterized and their clinical relevance is unknown. Such non-specific effects may not be limited to OPV, as other live vaccines have also been associated with non-specific protective effects (such as BCG vaccine against tuberculosis). Nonlive vaccines in contrast do not seem to have the same effects.

The exact mechanism of non-specific protection induced by live vaccines needs to be elucidated further. Clinical studies could begin immediately because the vaccines in question are licensed and have an excellent safety record. Clinical trials involving off-label use of various drugs licensed for other indications are currently underway. The existing scientific rationale suggests that the same should be done for OPV and other live vaccines. A study is currently being discussed with various partners and vaccine manufacturers, including the US FDA, the outcomes of which will be carefully assessed to determine potential use in the context of the spread of SARS-CoV2 until the time when specific vaccines and antiviral therapies are ready.

From: Kadlec, Robert (OS/ASPR/IO) (b) (6)

Sent: Thursday, April 30, 2020 10:28 AM

To: Gallo, Robert (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)

Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Shuy, Bryan (OS/ASPR/IO)

<(b) (6)>

Subject: Re: Response

COLL0000018274-2515369

Dr Gallo thank you for your note and I appreciate you reaching out to me. I have copied Dr Collins and Dr Tabak to consider the ACTIV forum they have created to bring industry academia and government to consider scientific base approaches That you have described. Dr Collins has organized a vaccine group and I assess could be the best and fastest place to discuss your concept. I am sure they will connect with you soonest

Best

Bob Kadlec.

Sent from my iPhone

On Apr 30, 2020, at 10:02 AM, Gallo, Robert (b) (6) > wrote:

Dear Dr. Kaldec,

I have not heard from you in over a week. You mentioned getting back to me in a day or two. Time is passing. I am asking you to look at OPV 1 plus 3 serotypes as a bivalent, completely safe vaccine with powerful stimulation of innate immunity lasting several weeks , which can be given a second or third time, and with a historical track record of preventing other infections from entirely different RNA viruses (such as protecting against influenza). Therefore, it should be really helpful for some months, and I think get us past a second wave of SARS-CoV-2, and help people return to work safely. I don't understand delays or apparent lack of interest. Who can possibly be against this? If you hear of hypothetical problems we can show you that these are false. Just ask the questions, and we can give you the evidence.

However, no answer from you suggests no interest and must quickly make alternative pathways. I am though quite surprised and fear you are receiving "fake news" if you will pardon the expression. Some have been against this who defend their old and failed position on polio eradication with their promotion of the use of the inactivated polio virus vaccine. Please note that in the US between 1962 and 1985 we received (safely) the oral polio (OPV). Moreover, if vaccinated already there has not been a single case of a complication and BILLIONS have received it. No it will not last long as innate immunity is short lived, but we strongly believe that we can break the back of the SARS-CoVID-2 spread. Also note that this is what Bill Gates is doing now in India and much of the Eastern hemisphere.

There are countries outside the US wanting to move fast on this. We are waiting for your reply.

Robert Gallo
Director, Institute of Human Virology,
Professor of Medicine and Professor of Microbiology,
UMB, School of Medicine, Baltimore,

And

Co-founder and International Science Advisor of the Global Virus Network (GVN)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/28/2020 9:02:34 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: WHO Act Accelerator Dialogue | Draft Agenda for Call on Friday, 5/29 @ 9AM ET

Thanks, Francis. I will do it.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 28, 2020 4:55 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)>
Subject: RE: WHO Act Accelerator Dialogue | Draft Agenda for Call on Friday, 5/29 @ 9AM ET

Sorry, we didn't get to this in our call this afternoon. I'm not sure how useful this might be – but it would probably be worth joining for an hour. It might provide some WHO insight.

David, if you can fit in to your calendar, you would be ideal.

Francis

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Thursday, May 28, 2020 2:14 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)>
Subject: FW: WHO Act Accelerator Dialogue | Draft Agenda for Call on Friday, 5/29 @ 9AM ET
Importance: High

How would NIH leadership like us to handle this request please? Can discuss on our 2:30 call. David

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Thursday, May 28, 2020 9:35 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: FW: WHO Act Accelerator Dialogue | Draft Agenda for Call on Friday, 5/29 @ 9AM ET
Importance: High

Hi David,

Should this be you to present at this given the level? I can try to do this, but would need to find someone to cover one of my ACTIV protocol writing team meetings.

Thanks,
Stacey

COLL0000017287-2515370

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Bugin, Kevin (b) (6)
Sent: Thursday, May 28, 2020 7:05 AM
To: Adam, Stacey (FNIH) [T] (b) (6)
Subject: FW: WHO Act Accelerator Dialogue | Draft Agenda for Call on Friday, 5/29 @ 9AM ET

See below. Let me know if someone from NIH/FNIH could join to give a few minutes overview of ACTIV—probably the Therapeutics side. Thanks,

Kevin

From: Ayala, Ana (OS/OGA) (b) (6) >
Sent: Wednesday, May 27, 2020 12:57 PM
To: Marks, Peter (b) (6) >; Woodcock, Janet (b) (6) ; Abdoo, Mark (b) (6) >; Disbrow, Gary (OS) (b) (6) >; Houchens, Christopher (OS) (b) (6) >; Johnson, Robert (OS) (b) (6) >
Cc: Kerr, Lawrence (OS) <(b) (6)>; Gruber, Marion (b) (6) ; Krause, Philip (b) (6) >; Thomas, Ashley (b) (6) >; Weinberger, Collin (OS) (b) (6) ; Moudy, Robin (OS) (b) (6) Lopez, Arnela (OS) <(b) (6)>
Subject: WHO Act Accelerator Dialogue | Draft Agenda for Call on Friday, 5/29 @ 9AM ET

Dear all,

Following up on Larry's outreach to you on starting WHO Act Accelerator dialogue with Dr. Soumya Swaminathan (Chief Scientist)/Mariangela Simão (ADG/ Drug Access, Vaccines and Pharmaceuticals) and their teams at WHO, **please find attached the draft agenda for your review and input. We kindly ask that you please send any comments by TOMORROW, Thursday (5/28), OOB.** These biweekly calls will start this Friday, 5/29, at 9am ET. Arnela Lopez will send the calendar invitation on Larry's behalf following this email. Many thanks, and please do not hesitate to reach out with any questions.

Warm regards,

Ana

Ana S. Ayala, J.D., LL.M.
Senior Global Health Officer
Pandemic and Emerging Threats
Office of Global Affairs
U.S. Department of Health and Human Services (HHS)
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Sent: 6/17/2020 12:47:07 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W (b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] (b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3b922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
[(b) (6) Elsaid, Olivia [(b) (6) Walker, Paula (NIH/NINDS) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes
[(b) (6) Sorosa, Alex David [(b) (6) Lumsden, Joanne (NIH/NCATS)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Freire, Maria (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcc]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment;
Untitled Attachment; Untitled Attachment; Canceled: ACTIV Therapeutics-Clinical Working Group Meeting; Untitled
Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled
Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled

Attachment; Canceled: ACTIV Therapeutics-Clinical Working Group Meeting; Canceled: ACTIV Therapeutics-Clinical Working Group Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: <https://fnih.zoom.> (b) (6)

Start: 6/25/2020 5:00:00 PM

End: 6/25/2020 6:00:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs every Thursday from 1:00 PM to 2:00 PM effective 6/25/2020 until 12/31/2020.

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Connelly, Sarah [(b) (6)]
Sent: 12/11/2020 2:48:30 PM
To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) [(b) (6)]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) [(b) (6)]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) [(b) (6)]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA [(b) (6)]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) [(b) (6)]
CC: (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702f9c28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) [(b) (6)]; Jansen, Kathrin [(b) (6) [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabhavathi Fernandes [(b) (6) [(b) (6)]; Diamond, Michael [(b) (6) [(b) (6)]; Rose Li [(b) (6) [(b) (6)]; Dana Carluccio [(b) (6) [(b) (6)]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 [(b) (6) Dave Frankowski [(b) (6) antoinette_baric
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
 Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
 Mason, Stephen [(b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
 [(b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-12-09_Preclinical_WG_vF.pdf; PRECLINICAL_Working Group_Agenda_20201208_v1.pptx

Dear Preclinical Working Group,

Thank you all for attending our ACTIV preclinical full working group meeting on Wednesday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Also, please take a moment to review the updated strategic objectives (attached) and let us know if you have any additions or amendments.

Best regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >
Sent: Friday, October 2, 2020 2:19 PM
To: Menetski, Joseph (FNIH) [T]; Connelly, Sarah
Subject: FW: ACTIV Preclinical full working group
When: Wednesday, December 9, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://fnih.zoom.us/j/ \(b\) \(6\) 9](https://fnih.zoom.us/j/ (b) (6) 9)

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >
Sent: Tuesday, April 14, 2020 6:43 PM
To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6)
Connelly, Sarah
Subject: ACTIV Preclinical full working group
When: Occurs every Wednesday effective 4/22/2020 until 12/23/2020 from 10:00 AM to 11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/14/2020 10:42:52 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6)
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(b) (6); (b) (6); (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
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CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D

(b) (6) Dave Frankowski [david. (b) (6) Baric, Toni C
(b) (6)

Subject: ACTIV Preclinical working group (Tuesday meeting)

Attachments: Untitled Attachment

Location: <https://zoom.us/> (b) (6)

Start: 4/21/2020 6:00:00 PM

End: 4/21/2020 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday from 2:00 PM to 3:00 PM

Required Attendees: (b) (6) (b) (6) ; (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) ; (b) (6) (b) (6) (b) (6) ;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 9/25/2020 4:57:18 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffels, Paul [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6)

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom.> (b) (6)

Start: 11/4/2020 3:00:00 PM

End: 11/4/2020 4:00:00 PM

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Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Miekko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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Sent: 5/1/2020 11:12:13 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: Update on other COVID "master protocol" efforts
Flag: Follow up

Hi Francis,

I sat in on several of the Working Group calls today and had my daily update with my team and one with Deloitte. I learned:

- The VA is working on a master protocol for COVID; Margaret Anderson thinks Mike Milken is behind this. Karen Tountas has arranged for our VA rep on the Clinical Trial Capacity Group, Victoria Davey, to set up a call with the VA MP folks and the ACTIV MP design Sub Group Stacey Adam is leading.
- From a presentation that Mike Poole of Gates Foundation gave us, their Tx Accelerator is arranging reasonably robust testing of many of the compounds we are looking to prioritize for ACTIV, including to our surprise mAbs. We still see daylight, but differentiation will be that much more challenging.
- NHLBI is actively designing an MP in their PETAL network for anticoagulants. Thanks to Cliff Lane, we are trying to get Amy Patterson to speak to Sarah Read and Stacey so we have some chance to decently align approaches.
- NINDS is both collaborating with NHLBI and running their own protocol using their SIREN network.

We cannot control what Milken and Gates do, but it is distressing to see efforts announced within NIH that more or less completely overlap and potentially compete for the same kinds of protocols and patients that ACTIV is attempting to address. It makes the partnership overall look disorganized. In fact one of our WG co-chairs used the chat feature on Zoom to comment on the side to one of my folks during a description of one of the other side NIH institute efforts that "this is like a circus—how do these people not talk to each other?"

This is not good. While you have my commitment that we will always do what we can to make sure we communicate to others in NIH the ACTIV plans, we are going to lose control of the public narrative overall if this continues. I think there is still time to address this; I would suggest a way be found to bring these other efforts together under the ACTIV banner and brand as soon as possible.

Regards,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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Sent: 6/30/2020 8:55:01 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]
Subject: RE: Invitation to virtual panel during WHO global research update tomorrow
Flag: Follow up

Thanks, will wait for the good word from Francis or Larry before proceeding.

From: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Sent: Tuesday, June 30, 2020 4:28 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Cc: Freire, Maria (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)>
Subject: Re: Invitation to virtual panel during WHO global research update tomorrow

I think it would be good if you were able to do this. I see it more important from a political than a scientific perspective.

Cliff

From: "Wholley, David (FNIH) [T]" <(b) (6)>
Date: Tuesday, June 30, 2020 at 3:14 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)> Lawrence Tabak <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Cc: "Freire, Maria (FNIH) [T]" <(b) (6)> "James, Stephanie (FNIH) [T]" <(b) (6)>
Subject: FW: Invitation to virtual panel during WHO global research update tomorrow

Francis, Larry, Cliff: how would you like this handled? I can make time on Thursday to do this if need be, but of course cannot make any commitments as regards international coordination. Regards, David

From: Handley, Gray (NIH/NIAID) [E] <(b) (6)>
Sent: Tuesday, June 30, 2020 12:50 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Marston, Hilary (NIH/NIAID) [E] <(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Kim, Peter (NIH/NIAID) [E] <(b) (6)>
Subject: FW: Invitation to virtual panel during WHO global research update tomorrow

David, As you may know, WHO is convening a large meeting July 1-2 (tomorrow and the next day) to provide a COVID R&D update for scientists around the world. The current draft agenda is attached. I can send information on registration if needed.

COLL0000018183-2515377

The WHO planners have just asked for US speakers to be on a panel to describe ACTIV and OWS. Because ACTIV includes a lot of activity outside NIAID purview, would you be willing to make yet another very short presentation summarizing that program as a member of this panel? You would have just a few minutes; but there also could be some questions. The panel is also being asked to discuss how international coordination can be enhanced. In the attached draft agenda, it is the last session on July 2, at what will be 10:30 a.m. our time. We are still looking for the right person to speak about OWS but since they mention a focus on vaccines, we may have someone from VRC do that one.

Please let me know your thoughts before we recommend to WHO that they invite you for the ACTIV description.

Thanks. Gray

From: "SATHIYAMOORTHY, Vaseeharan" <(b) (6)>
Date: Tuesday, June 30, 2020 at 10:55 AM
To: Hilary Marston (b) (6) >
Subject: Invitation to virtual panel during WHO global research update tomorrow

Hi Hilary,

I hope you're well.

Had you heard that we are holding a virtual global COVID19 research forum on July 1-2? I am writing to ask if you would agree to speak for 5 minutes as attached in a panel on initiatives related to COVID19 therapeutics?

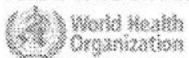
This is tomorrow – apologies for the last minute request. It has all been organized at short notice. We have over 1000 scientists registered to listen in, following on from the Feb 11-12 in-person forum that led to the roadmap that we published.

If you would like to talk to me for some background, please feel free to call on +41 79 540 6919. Hopefully the agenda is self-explanatory.

Many thanks
With kind regards
Vasee

Vasee Moorthy BA MA BMBCh MRCP PhD,
Senior Advisor, R&D Blueprint co-lead,
Science Division,
World Health Organization Headquarters,
Geneva, Switzerland

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- Please note that access to the virtual meeting will be provided **only to those who have registered.**

For any questions, please address these to Neddy (b) (6)) and Charity (b) (6) .

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Sent: 5/18/2020 3:46:05 PM
To: Jansen, Kathrin [(b) (6)]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public
Flag: Follow up

Thanks!

From: Jansen, Kathrin < (b) (6) >
Sent: Monday, May 18, 2020 11:01 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Myles, Renate (NIH/OD) [E] < (b) (6) >
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Dear Francis, I missed my deadline, thanks for the prompt. Ok to use my name as a co-chair. Best Kathrin

From: Collins, Francis (NIH/OD) [E] (b) (6) >
Sent: Monday, May 18, 2020 9:58 AM
To: Jansen, Kathrin (b) (6)
Cc: Myles, Renate (NIH/OD) [E] (b) (6)
Subject: [EXTERNAL] NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, May 16, 2020 6:02 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Myles, Renate (NIH/OD) [E] < (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6)
Subject: URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.**

COLL0000020335-2515378

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/6/2020 4:55:20 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures
Flag: Follow up

Not that I can see.

Did anyone else get any, David?

Joe

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, June 6, 2020 12:53 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

OK. Did we get any read-ahead material from Jacqueline?

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Saturday, June 6, 2020 12:53 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >; Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6) >
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

The meeting has these invites.

Wholley, David (FNIH) [T]
Adam, Stacey (FNIH) [T]
Menetski, Joseph (FNIH) [T]
Jacqueline Kirchner
Woodcock, Janet (FDA/CDER)
Collins, Francis (NIH/OD) [E]

COLL0000017546-2515379

joe

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, June 6, 2020 12:50 PM
To: Wholley, David (FNIH) [T] (b) (6); Menetski, Joseph (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6) >; Wood, Gretchen (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6)
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Sincere apologies, I just saw this message. I don't know who has been invited to join this call, can someone fill me in?

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Saturday, June 6, 2020 7:21 AM
To: Menetski, Joseph (FNIH) [T] <(b) (6)>; Collins, Francis (NIH/OD) [E] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6) >; Wood, Gretchen (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] (b) (6); Adam, Stacey (FNIH) [T] (b) (6)
Subject: Re: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

I noticed a label on today's call "data shared in confidence". Does this give us pause in terms of inviting additional experts?

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From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Friday, June 5, 2020 6:43:53 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6); Menetski, Joseph (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6)
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

COLL0000017546-2515379

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2:45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

Saturday call with J Kirchner:

Peter Adams, (OS/ASPR/BARDA); (b) (6)

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6)

John W Mellors at University of Pittsburgh; (b) (6)

Monday call with Skip Virgin:

Peter Adams, (OS/ASPR/BARDA); (b) (6)

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6)

John W Mellors at University of Pittsburgh; (b) (6)

Randall Tressler, (NIH/NIAID); (b) (6)

Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) | fnihi.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnihi.org/pandemic



From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 6/17/2020 7:55:19 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [(b) (6)] Cavaleri, Marco [(b) (6)] Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6)] Corey, Larry [(b) (6)] Culp, Michelle (NIH/OD) [E] [(b) (6)] Disbrow, Gary (OS/ASPR/BARDA) [(b) (6)] Dolsten, Mikael [(b) (6)] Erbeling, Emily (NIH/NIAID) [E] [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [(b) (6)] Gibbons, Gary (NIH/NHLBI) [E] [(b) (6)] Hudson, Thomas [(b) (6)] James, Stephanie (FNIH) [T] [(b) (6)] Johnson, Robert (OS/ASPR/BARDA) [(b) (6)] Kramer, Lynn [(b) (6)] Lane, Cliff (NIH/NIAID) [E] [(b) (6)] Lepore, John [(b) (6)] Marks, Peter (FDA/CBER) [(b) (6)] Marston, Hilary (NIH/NIAID) [E] [(b) (6)] Mascola, John (NIH/VRC) [E] [(b) (6)] Meeker, David [(b) (6)] Menetski, Joseph (FNIH) [T] [(b) (6)] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6)] Pangalos, Mene [(b) (6)]; Pao, William [(b) (6)] Parker, Ashley (NIH/OD) [E] [(b) (6)]; Perlmutter, Roger [(b) (6)] Plenge, Robert [(b) (6)] Plump, Andy [(b) (6)] Rachel Ramoni [(b) (6)] Rasi, Guido [(b) (6)]; Reed, John [(b) (6)] Reese, David [(b) (6)] Rouse, Doris [(b) (6)] Santos, Michael (FNIH) [T] [(b) (6)] Skovronsky, Daniel [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)] Stoffels, Paul [(b) (6)]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6)] Tsai, John [(b) (6)] Vessey, Rupert [(b) (6)]; Virgin, Skip [(b) (6)] Wholley, David (FNIH) [T] [(b) (6)] Woodcock, Janet (FDA/CDER) [(b) (6)] Young, John [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [(b) (6)] Desrosiers, Betsy [(b) (6)] Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [(b) (6)] Lowy, Douglas (NCI) [(b) (6)] Read, Sarah (NIH/NIAID) [E] [(b) (6)] Anderson, James (NIH/OD) [E] [(b) (6)] Burklow, John (NIH/OD) [E] [(b) (6)]; Castillejos, Carlos [(b) (6)] Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Myles, Renate (NIH/OD) [E] [(b) (6)] Wolinetz, Carrie (NIH/OD) [E] [(b) (6)] Bancel, Stephane [(b) (6)] Erck, Stan [(b) (6)]

Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lee, William [(b) (6)] Paul, Steve [(b) (6)]

CC: Adam, Stacey (FNIH) [T] [(b) (6)] Alvarez, Rosa [(b) (6)] Anderson, Margaret [(b) (6)] Chen, Helen [(b) (6)] oelsaid [(b) (6)] Gonzalez, Nina [(b) (6)] Stratton, Ben [(b) (6)] Tolman, Brett [(b) (6)] Tountas, Karen (FNIH) [T] [(b) (6)] Wachtel, Jonathan [(b) (6)] Togashi, Mieko (NIH/NCI) [E] [(b) (6)] Underwood, Nancy [(b) (6)] Zottoli, Jessica [(b) (6)] Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)] Carver, Trea (NIH) [C] [(b) (6)]; Hardesty, Rebecca (NIH/OD) [E] [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [(b) (6)] Sepulveda, Dorina (FNIH) [T] [dsepu (b) (6)] Simon, Dina (NIH/OD) [C] [(b) (6)] Austin, Sarah (NIH/NIAID) [E] [(b) (6)] Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)] Conrad, Patricia (NIH/NIAID) [E] [(b) (6)] Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; Edl, Susan [(b) (6)] Giorgi, Sara [sara. (b) (6)] Hoban, Michelle [(b) (6)] Hoffstetter, Renata (FNIH) [T] [(b) (6)] Iberdemaj, Vaide [va (b) (6)] McManus, Ayanna (NIH/OD) [E] [ayanna. (b) (6)] Minnich, Beth [(b) (6)] Perala, Mie [(b) (6)] Protasiewicz, Ann [(b) (6)] Riccobene, Kim [(b) (6)] Suhana, Tina (NIH/VRC) [E] [(b) (6)]; Thomas, Ashley (FDA/CDER) [(b) (6)] Wood, Gretchen (NIH/OD) [E] [(b) (6)] Gladman, Jordan (NIH/OD) [E] [(b) (6)]; FNIH Central Account [(b) (6)] Ripley, Nadege [(b) (6)] Riggan, Mary [(b) (6)] Vessey, Rupert [(b) (6)] Lowy, Douglas (NIH/NCI) [E] [(b) (6)] Gorman, Greta (FNIH) [T] [(b) (6)] Lucas Smalldon

[(b) (6) Klotz, Mary (Molly) [(b) (6)]; Victoria Davey
 [(b) (6) Hodes, Richard (NIH/NIA) [E] [(b) (6) Bronson, Charlette (NIH/NIA) [E]
 [(b) (6) Best, Cindy (NIH/NEI) [E] [(b) (6)]; Tumminia, Santa (NIH/NEI) [E]
 [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E]
 [(b) (6) Koob, George (NIH/NIAAA) [E] [(b) (6)]; Rodgers, Griffin (NIH/NIDDK)
 [E] [(b) (6) Woychik, Rick (NIH/NIEHS) [E] [(b) (6) Higginbotham, Aurelia
 (NIH/NIAAA) [E] [(b) (6)]; Shapiro, Beth (NIH/NIDDK) [E] [(b) (6) Eason,
 Allison (NIH/NIEHS) [E] [(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6) Volkow,
 Nora (NIH/NIDA) [E] [(b) (6) Glass, Roger (NIH/FIC) [E] [(b) (6) Tucci, Debara
 (NIH/NIDCD) [E] [(b) (6) Byrnes, Noni (NIH/CSR) [E] [(b) (6) Schulke, Hilda
 (NIH/NIDA) [E] [(b) (6) Stover, Kathleen (NIH/FIC) [E] [(b) (6)]; Hamid, Khawar
 (NIH/CSR) [E] [(b) (6) Norris, Andrea (NIH/CIT) [E] [(b) (6) Wade, Portia
 (NIH/CIT) [E] [(b) (6)] [(b) (6) Anita Caulfield [(b) (6)]
 Sharpless, Norman (NIH/NCI) [E] [(b) (6) Bianchi, Diana (NIH/NICHD) [E]
 [(b) (6) Ott, Sandra (NIH/NICHD) [E] [(b) (6) Ramirez, Katherine (NIH/NIMHD) [C]
 [(b) (6) Perez-Stable, Eliseo (NIH/NIMHD) [E] [(b) (6) Council, Lisa
 (NIH/NCCIH) [E] [(b) (6) Langevin, Helene (NIH/NCCIH) [E] [(b) (6)]; Schwetz, Tara
 (NIH/OD) [E] [(b) (6)]; Dzikoto-Pomenya, Caroline (NIH/OD) [C] [(b) (6)]
 [(b) (6)]

Subject: ACTIV Leadership Call #6

Location: <https://fnih.zoom.us/j/9181157171> [(b) (6)]

Start: 7/29/2020 6:30:00 PM

End: 7/29/2020 8:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bancel, Stephane; Erck, Stan

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Togashi, Mieke (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; FNIH Central Account; Ripley, Nadege; Riggan, Mary; Vessey, Rupert; Lowy, Douglas (NIH/NCI) [E]; Gorman, Greta (FNIH) [T]; Lucas Smalldon; Klotz, Mary (Molly); Victoria Davey; Hodes, Richard (NIH/NIA) [E]; Bronson, Charlette (NIH/NIA) [E]; Best, Cindy (NIH/NEI) [E]; Tumminia, Santa (NIH/NEI) [E]; Meltzer, Abbey (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Koob, George (NIH/NIAAA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Woychik, Rick (NIH/NIEHS) [E]; Higginbotham, Aurelia (NIH/NIAAA) [E]; Shapiro, Beth (NIH/NIDDK) [E]; Eason, Allison (NIH/NIEHS) [E]; Walker, Paula (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Glass, Roger (NIH/FIC) [E]; Tucci, Debara (NIH/NIDCD) [E]; Byrnes, Noni (NIH/CSR) [E]; Schulke, Hilda (NIH/NIDA) [E]; Stover, Kathleen (NIH/FIC) [E]; Hamid, Khawar (NIH/CSR) [E]; Norris, Andrea (NIH/CIT) [E]; Wade, Portia (NIH/CIT) [E]; [(b) (6)] Anita Caulfield; Sharpless, Norman (NIH/NCI) [E]; Bianchi,

Diana (NIH/NICHD) [E]; Ott, Sandra (NIH/NICHD) [E]; Ramirez, Katherine (NIH/NIMHD) [C]; Perez-Stable, Eliseo (NIH/NIMHD) [E]; Council, Lisa (NIH/NCCIH) [E]; Langevin, Helene (NIH/NCCIH) [E]; Schwetz, Tara (NIH/OD) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/26/2020 3:50:34 AM
To: Paul Klekotka [(b) (6)]; Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [(b) (6)]; Gelijns, Annetine [(b) (6)]; Moskowitz, Alan [(b) (6)]; Ab Babiker [(b) (6)]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6)]; [(b) (6)]; Birgit Grund [(b) (6)]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [(b) (6)]; David Vock [(b) (6)]; Thomas Murray [(b) (6)]; Max Parmar [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; [(b) (6)]; [(b) (6)]; [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [(b) (6)]; [(b) (6)]; Ajay Nirula [(b) (6)]; Ginde, Adit [(b) (6)]; Andrew Phillips [(b) (6)]; [(b) (6)]; Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; Shweta Sharma [(b) (6)]; [(b) (6)]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Chew, Kara M.D. [(b) (6)]; [(b) (6)]; .edu]; Daar, Eric [(b) (6)]; Bagiella, Emilia [(b) (6)]; [(b) (6)]; Lisbeth Jørgensen [lisbeth. [(b) (6)]; Erhardt, William (HHS/IOS) [(b) (6)]; [(b) (6)]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/21/2020 7:13:59 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6)] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6)] Plump, Andrew [(b) (6)] Stoffels, Paul [(b) (6)] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6)] Anderson, Margaret [(b) (6)] Chen, Helen [(b) (6)] Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [(b) (6)] Tolman, Brett [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos [(b) (6)]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [(b) (6)] Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hardesty, Rebecca
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
 [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Gorman, Greta (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Barasch, Kimberly
 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie
 [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim
 [(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
 [(b) (6) Zottoli, Jessica [(b) (6)

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 8/14/2020 7:30:00 PM

End: 8/14/2020 9:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
[\(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))

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Passcode: (b) (6)
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Find your local number: [\(b\) \(6\)](https://fnih.zoom.us (b) (6))

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/1/2020 6:13:17 PM
Subject: *ACTIV Vaccine Discussion
Location: Zoom link in the calendar entry
Start: 5/2/2020 8:00:00 PM
End: 5/2/2020 9:00:00 PM
Show Time As: Busy

Recurrence: (none)

Meeting to discuss ACTIV vaccines program

Join Zoom Meeting

<https://fnih.zoom.us/j/91012345678> (b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

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US (Germantown)

US (New York)

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US (New York)

US (Chicago)

US (San Jose)

US (Tacoma)

US (Houston)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/j/91012345678> (b) (6)

Hi Patty,

Thanks so much. I believe we now have agreement from everyone on 4pm tomorrow, with the completely understandable caveat about Tony's schedule. I will send an invite soon.

Thanks,
Mike

COLL0000011089-2515383

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Conrad, Patricia (NIH/NIAID) [E] (b) (6)

Sent: Friday, May 1, 2020 1:31 PM

To: Santos, Michael (FNIH) [T] <(b) (6)>; Barasch, Kimberly (NIH/NIAID) [C]
(b) (6)

Cc: Tolman, Brett (b) (6) >; Wood, Gretchen (NIH/OD) [E] (b) (6) ; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Barasch, Kimberly (NIH/NIAID) [C] <(b) (6)>; Awwad, David (NIH/NIAID) [C] (b) (6) >

Subject: RE: Call with Vaccines WG co-chairs

Hi Mike-

4 pm tomorrow should be fine. Please know that Dr. Fauci's calendar is always subject to change given he is often called to the White House. Will do our best to keep this on.

Please include both Kim and David – both cc'd here – with any calendar makers/adjustments.

Many thanks,
-patty

From: Santos, Michael (FNIH) [T] (b) (6)

Sent: Friday, May 1, 2020 12:35 PM

To: Conrad, Patricia (NIH/NIAID) [E] (b) (6) ; Barasch, Kimberly (NIH/NIAID) [C]
(b) (6) >

Cc: Tolman, Brett (b) (6) ; Wood, Gretchen (NIH/OD) [E] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6)

Subject: RE: Call with Vaccines WG co-chairs

Thanks, Gretchen!

Hi Patty and Kim,

Francis is trying to set up a meeting this weekend with Tony, Cliff Lane, John Mascola, Peter Marks, Kathrin Jansen, Doug Lowy, David Wholley, and me. The note below says that tomorrow is better for Tony than Sunday. Based on what I know so far, tomorrow 4pm or later seems to be the overlap in availability (pending hearing from John and Peter Marks). Would 4pm or later work for Tony?

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wood, Gretchen (NIH/OD) [E] <(b) (6)>

Sent: Friday, May 1, 2020 12:30 PM

To: Santos, Michael (FNIH) [T] (b) (6)

COLL0000011089-2515383

Cc: Tolman, Brett <(b) (6)>; Melencio, Cheryl (FNIH) [T] (b) (6); Conrad, Patricia (NIH/NIAID) [E] (b) (6); Barasch, Kimberly (NIH/NIAID) [C] <(b) (6)>

Subject: Re: Call with Vaccines WG co-chairs

Hi Mike,

Sure, I have cc'd Patty and Kim from Dr. Fauci's office. They can help.

Best wishes,

Gretchen

From: "Santos, Michael (FNIH) [T]" (b) (6)

Date: Friday, May 1, 2020 at 12:25 PM

To: Gretchen Wood (b) (6)

Cc: "Tolman, Brett" (b) (6); "Melencio, Cheryl (FNIH) [T]" (b) (6) >

Subject: FW: Call with Vaccines WG co-chairs

Hi Gretchen,

It looks like we're scheduling a meeting tomorrow with Francis, Toni Fauci, Cliff Lane, John Mascola, Peter Marks, Kathrin Jansen, Doug Lowy, David Wholley, and me.

Do you have advice on how best to schedule with Toni Fauci – whom should I contact? I think I have the information to schedule with the rest of them.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] (b) (6)

Sent: Friday, May 1, 2020 9:22 AM

To: Santos, Michael (FNIH) [T] (b) (6)

Subject: FW: Call with Vaccines WG co-chairs

From: Lane, Cliff (NIH/NIAID) [E] (b) (6)

Sent: Friday, May 1, 2020 9:19 AM

To: Collins, Francis (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <(b) (6)>;

Freire, Maria (FNIH) [T] (b) (6); Tabak, Lawrence (NIH/OD) [E] <(b) (6)>;

Parker, Ashley (NIH/OD) [E] <(b) (6)>

Cc: Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E]

(b) (6)

Subject: Re: Call with Vaccines WG co-chairs

2-4 is bad for me.

Cliff

From: "Collins, Francis (NIH/OD) [E]" (b) (6) >
Date: Friday, May 1, 2020 at 9:15 AM
To: "Wholley, David (FNIH) [T]" (b) (6) >, "Freire, Maria (FNIH) [T]" < (b) (6) > Lawrence Tabak (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, "Parker, Ashley (NIH/OD) [E]" (b) (6) >, "Anderson, James (NIH/OD) [E]" (b) (6) >
Cc: "Wood, Gretchen (NIH/OD) [E]" (b) (6) >, "McManus, Ayanna (NIH/OD) [E]" (b) (6) >
Subject: Call with Vaccines WG co-chairs

Hi David,

Tony says yes to joining. Agrees we should also have Peter Marks. Also wants John Mascola and Cliff Lane.

Saturday is better for Tony. I can make myself available anytime except 8:30 – 9:15. Can you work on that?

FC

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/11/2020 1:59:52 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Re: slides from today and ACTIV Vaccine Committee
Flag: Follow up

Francis

Despite the reassurance on the call today that the issues have been socialized with the WG, I recommend that we do have a separate discussion with them. We should do everything possible to make this transition as smoothly as possible.
Larry

From: Francis Collins <(b) (6)>
Date: Sunday, May 10, 2020 at 9:52 PM
To: "Wholley, David (FNIH) [T]" <(b) (6)> "Santos, Michael (FNIH) [T]" <(b) (6)>
"Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: FW: slides from today and ACTIV Vaccine Committee

See slides and note from Larry Corey.

Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?

FC

From: Corey MD, Larry <(b) (6)>
Sent: Sunday, May 10, 2020 9:35 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Subject: slides from today and ACTIV Vaccine Committee

Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements ; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of the harmonized design ; she voices the issue all Pharma companies have in a real viable market ; they don't want head to head comparisons ; parallel universes is how they always operate .
The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.

If there are other issues of concern just call My cell is (b) (6) .
Thanks Larry

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 12/20/2020 2:34:37 AM
To: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Further Summary on Ivermectin ACTIV Review
Attachments: Ivermectin.pptx

Hi Janet—there have been a number of inquiries from the Hill regarding ivermectin. Thought you should know about the information regarding ACTIV review of this agent that we have sent to Francis earlier this evening. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Saturday, December 19, 2020 8:42 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Subject: Further Summary on Ivermectin ACTIV Review

Hi Francis,

In case it is of use in your interactions with Senator Johnson or other future inquiries, below and attached is a complete description of the review of ivermectin by the ACTIV team, courtesy of Stacey Adam of course. If OK with you I would like to share this with Janet Woodcock so everyone is in sync. David

1. Ivermectin was first reviewed in Wave 1. It made it through the initial triage of 400 agents by ACTIV and was scored in the antiviral subteam of the Therapeutics Clinical Working Group assigned to look at such agents. It scored moderately well due to the anecdotal data from its use in the clinic in Peru and other countries, and several early, though inadequately powered and inconclusive, case studies. However, the preclinical data for ivermectin's mechanism of action were very weak, and since none of the clinical information was from controlled trials, the review team felt more information was needed in order to place it into a large confirmatory trial. In addition, the group felt there were higher priority repurposed agents to pursue at the time (a continuing theme; see attached slides for review meeting summary)
2. Inhaled ivermectin was reviewed in Wave 2. But in this instance the formulation that was submitted to ACTIV for consideration was significantly lacking in the PK/PD data needed to suggest that it would indeed be effective in patients. It did not score well in the clinical antiviral subteam, so the ACTIV Preclinical Working Group then took it up to see if there could be a match for preclinical testing resources in NIAID. The prior/ongoing studies for both the inhaled and the oral formulation of ivermectin; these are currently pending and will be reviewed by ACTIV as soon as they are available (see attached slides review meeting and agent review summary).
3. Oral ivermectin was reviewed by the ACTIV team yet again, as part of our 3rd Round of Wave 3 review of agents. (It is worth noting here that these reviews are part of a very urgent but also intensive effort, having taking place virtually on a weekly basis since May, often on weekends.) At this point, the group determined that the preclinical data showing any potential antiviral mechanism of action of ivermectin was still weak, and that they would be far more comfortable waiting to see the results of the NIAID preclinical studies that were set up through the ACTIV Preclinical WG (and which are still ongoing). In addition, it was noted that a number of Phase 2 randomized clinical trials across the world had been begun by other groups: at least one here in the US (UPenn), one in the EU (sponsored by Gates), and one in Japan. These studies should be complete or nearly completed soon, although we have yet to see any public release of their results.

4. Given the impending availability of preclinical NIAID testing data and the data from the existing clinical studies—which would provide further and better controlled experimental results to more definitively either reinforce or contradict the suggestions from the earlier case studies that ivermectin might be an effective treatment for COVID-19--the team from ACTIV that studies antiviral agents decided to defer further consideration of the agent until those data are available and able to be reviewed. (see attached slides review meeting and agent review summary)
5. Furthermore, since this review by the ACTIV antiviral team, data has very recently emerged in the scientific literature and from some other presentations to the ACTIV team that suggest that the effects of ivermectin might in fact not be antiviral, but could be instead related to host-targeted/immune-modulatory mechanisms of action. In consequence of this, the ACTIV TX-Clinical WG co-chairs have recommended that the data on ivermectin be yet again further reviewed by the ACTIV team that evaluates immune modulators to make doubly sure whether there is any value in the agent from that perspective, given that group's specific scientific expertise. This review is expected to take place by January 15.

As you know, ACTIV has reviewed literally hundreds of drugs since its inception in April in order to select those agents that are most promising for further study, and as a result has numerous immune modulators, antiviral drugs (including monoclonal antibodies), anti-inflammatory agents, and anti-thrombotics currently in clinical testing in the various ACTIV master protocols. While we are still assessing whether ivermectin is at all effective in treating COVID-19 and why, the ultimate question is of course whether ivermectin is sufficiently more effective against COVID19 than those treatments already being tested through ACTIV or other potential treatments we are in the process of assessing, and therefore why it should be worth not just the considerable cost of such testing in terms of USG financial resources, but probably more importantly why it could be worth the additional allocation of increasingly scarce resources to conduct crucial clinical trials of COVID-19 agents within our already overburdened U.S. healthcare system.

Please let me know if you have further questions. Thanks, David

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/6/2020 4:53:25 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

OK. Did we get any read-ahead material from Jacqueline?

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Saturday, June 6, 2020 12:53 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

The meeting has these invites.

Wholley, David (FNIH) [T]
Adam, Stacey (FNIH) [T]
Menetski, Joseph (FNIH) [T]
Jacqueline Kirchner
Woodcock, Janet (FDA/CDER)
Collins, Francis (NIH/OD) [E]

joe

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, June 6, 2020 12:50 PM
To: Wholley, David (FNIH) [T] <(b) (6)> >; Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> ; Melencio, Cheryl (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Sincere apologies, I just saw this message. I don't know who has been invited to join this call, can someone fill me in?

From: Wholley, David (FNIH) [(b) (6)]
Sent: Saturday, June 6, 2020 7:21 AM
To: Menetski, Joseph (FNIH) [T] < (b) (6) >; Collins, Francis (NIH/OD) [E] < (b) (6) >; Adam, Stacey (FNIH) [T] < (b) (6) > Melencio, Cheryl (FNIH) [T] (b) (6) Wood, Gretchen (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) >
Subject: Re: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

I noticed a label on today's call "data shared in confidence". Does this give us pause in terms of inviting additional experts?

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From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Friday, June 5, 2020 6:43:53 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Wholley, David (FNIH) [T] (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) >
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2:45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

COLL0000020645-2515386

Saturday call with J Kirchner:

Peter Adams, (OS/ASPR/BARDA); (b) (6) v

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6) i

John W Mellors at University of Pittsburgh; (b) (6) u

Monday call with Skip Virgin:

Peter Adams, (OS/ASPR/BARDA); (b) (6)

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6)

John W Mellors at University of Pittsburgh; (b) (6)

Randall Tressler, (NIH/NIAID); (b) (6)

Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) | fnih.org

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From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/11/2020 2:35:43 AM
To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
CC: Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: FW: slides from today and ACTIV Vaccine Committee

Need to participate in this tomorrow 11:15-11:45, so Julie will need to be rescheduled.
Sorry
Larry

From: Francis Collins <(b) (6)>
Date: Sunday, May 10, 2020 at 10:32 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Santos, Michael (FNIH) [T]" <(b) (6)> "Wholley, David (FNIH) [T]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: RE: slides from today and ACTIV Vaccine Committee

That would be great.

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Sent: Sunday, May 10, 2020 10:32 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Subject: Re: slides from today and ACTIV Vaccine Committee

I can join if you would like me to.

From: Francis Collins <(b) (6)>
Date: Sunday, May 10, 2020 at 10:25 PM
To: "Santos, Michael (FNIH) [T]" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Wholley, David (FNIH) [T]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: RE: slides from today and ACTIV Vaccine Committee

I can probably make that work. Please send information about how to link in.

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Sunday, May 10, 2020 10:09 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> > Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> > Lane, Cliff (NIH/NIAID) [E] <(b) (6)> >
Subject: RE: slides from today and ACTIV Vaccine Committee

Hi Francis,

I have a regularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (Monday) morning. If you can be free then and would like to join, that's an option. If that doesn't work, we can find another time before the Wednesday meeting (1pm).

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Tabak, Lawrence (NIH/OD) [E] (b) (6) <v>
Sent: Sunday, May 10, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >
Subject: Re: slides from today and ACTIV Vaccine Committee

Francis
Despite the reassurance on the call today that the issues have been socialized with the WG, I recommend that we do have a separate discussion with them. We should do everything possible to make this transition as smoothly as possible.
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To: "Wholley, David (FNIH) [T]" <(b) (6)>, "Santos, Michael (FNIH) [T]" <(b) (6)>, "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)>, "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: FW: slides from today and ACTIV Vaccine Committee

See slides and note from Larry Corey.

Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?

FC

From: Corey MD, Larry <(b) (6)>
Sent: Sunday, May 10, 2020 9:35 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: slides from today and ACTIV Vaccine Committee

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the harmonized design ; she voices the issue all Pharma companies have in a real viable market ; they don't want head to head comparisons ; parallel universes is how they always operate .
The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.
If there are other issues of concern just call My cell is (b) (6) .
Thanks Larry

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/12/2020 5:10:22 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6)]; Vessey, Rupert [(b) (6) m]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]

CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange

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Lever, Susan (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
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Minnich, Beth (b) (6) Perala, Mie (b) (6) Protasiewicz, Ann
[ann. (b) (6) Riccobene, Kim (b) (6) Riffin, Mary (b) (6)
Ripley, Nadege (b) (6) Schuster, Donna (b) (6) Sepulveda,
Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Tajalli, Ada (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
[(b) (6) Zottoli, Jessica (b) (6)

Subject: ACTIV Leadership Team Meeting #11

Location: https://fnih.zoom.us/ (b) (6)

Start: 12/16/2020 3:00:00 PM

End: 12/16/2020 4:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 10/10/2020 6:21:38 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Roster of ACTIV Vaccines WG
Flag: Follow up

Hi Francis,

We don't maintain as nice of a version of the Sub-Group rosters, but here is the Clinical Trials Sub-Group list of names and organizations (some of which overlap with the main WG). We also commonly have additional guests depending on the topic, so if there's an organization or expertise that you're looking for that is not represented, we can invite them to a meeting ad hoc.

Thanks,
Mike

Name	Organization
Paula Annunziato (co-chair)	Merck
Larry Corey (co-chair)	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douguilh	J&J
Peter Dull	Gates
Emilio Emini	Gates
Emily Erbeling	NIAID/NIH
Gregory M. Glenn	Novavax
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Marion Gruber	CBER/FDA
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Peter Hotez	Baylor and Texas Children's
Laurent Humeau	Inovio
Kathrin Jansen	Pfizer
Cheryl Keech	Novavax

Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Paul Offit	Penn/CHOP
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna
Tal Zaks	Moderna

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Saturday, October 10, 2020 12:47 PM

To: Santos, Michael (FNIH) [T] <(b) (6)>

Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>

Subject: RE: Roster of ACTIV Vaccines WG

Thanks, this is helpful. Have you got a roster of the Clinical Trials Sub-Group?

From: Santos, Michael (FNIH) [T] <(b) (6)>

Sent: Saturday, October 10, 2020 11:47 AM

To: Collins, Francis (NIH/OD) [E] <(b) (6)>

Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

COLL0000013773-2515390

Sure, I'd be happy to convene a meeting of the WG.

The WG membership is attached. We also have a wider group of people that have been part of the sub-groups, so depending on the topic and the ask we could invite them as well (e.g., for a clinical trials question we could convene the WG plus the Clinical Trials Sub-Group).

For next steps, if we can know a little more about the topic and the desired timing, I'm happy to connect with Kathrin and Doug and schedule a meeting with the appropriate set of people.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, October 10, 2020 11:33 AM
To: Santos, Michael (FNIH) [T] (b) (6) >
Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6)
Subject: Roster of ACTIV Vaccines WG

Hi Mike,

We might need to reconvene the ACTIV Vaccines WG for some advice about management of next steps for the trials. Can you send me the roster?

Francis

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 5/14/2020 1:19:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: ChAdOx1

Just jumping in briefly to say that Ashley has mentioned some disquiet to me – prior to this email – that the industry chair of this WG seemed conflicted. She said it felt like KJ was deliberately slowing down the WG in the interests of Pfizer, but since the NIH folks on the group didn't push back she wasn't sure if she was misreading things. She doesn't know the players involved and neither do I, so take that observation for whatever it's worth. But thought it was more interesting in light of this email from John.

From: Mascola, John (NIH/VRC) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter (FDA/CBER) <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter <(b) (6)>
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)

(b) (5)

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Happy to discuss

further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH) (b) (6) >; Lane, Henry C (NIH) (b) (6) ; Marks, Peter (b) (6)

Cc: Fauci, Anthony S (NIH) <(b) (6)>; Wholley, David N (NIH) <(b) (6)>; Tabak, Lawrence A (NIH) (b) (6) >; Parker, Ashley S (NIH) <(b) (6)>

Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/8/2020 4:28:43 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6)] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6)] Plump, Andrew [(b) (6)] Stoffels, Paul [(b) (6)] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)] Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6)] Anderson, Margaret [(b) (6)] Chen, Helen [(b) (6)] Elsaid, Olivia [(b) (6)] Gonzalez, Nina [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [(b) (6)] Tolman, Brett [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie [(b) (6)] Protasiewicz, Ann [(b) (6)] Riccobene, Kim [(b) (6)] Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Zottoli, Jessica
 [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Burklow, John (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Gorman, Greta (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Hallett, Adrienne
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Meltzer, Abbey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Culp, Michelle (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Lane, Cliff (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Burrus-Shaw, Cyndi (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hardesty, Rebecca
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Castillejos, Carlos
 [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; FNIH Central Account
 [(b) (6) Lucas Smalldon [(b) (6) Gadbois, Ellen (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: ACTIV EC & Working Group Co-Chair Meeting
Attachments: 7.15 ACTIV Executive Committee Meeting 20200714 vFinal.pdf; 2020-06-
 17_Executive_Committee_Meeting_Summary vFinal.docx; 2020-07-
 01_ACTIV_Leadership_Team_Meeting_Summary FINAL.docx
Location: https://fnih.zoom.us/j, (b) (6)
Start: 7/15/2020 7:00:00 PM
End: 7/15/2020 8:30:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E];
 Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock,

**Optional
Attendees:**

Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica; Sepulveda, Dorina (FNIH) [T]; Burklow, John (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Hallett, Adrienne (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Castillejos, Carlos; Lowy, Douglas (NIH/NCI) [E]; FNIH Central Account; Lucas Smalldon

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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Password: (b) (6)

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/15/2020 6:08:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups
Attachments: Master list for ACTIV 041520.xlsx

Francis – the following emails were missing from the list that went out, please see 8 emails listed below.

Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) >
Kim, Elizabeth < (b) (6) >
Marston, Hilary (NIH/NIAID) [E] < (b) (6) >
Paul, Steve < (b) (6) >
Payne, David < (b) (6) >
Plump, Andy < (b) (6) >
Santos, Nancy < (b) (6) >
Shen, Yuan Li (FDA/CDER) < (b) (6) >

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, April 15, 2020 11:39 AM
To: Melencio, Cheryl (FNIH) [T] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

From: Melencio, Cheryl (FNIH) [T] < (b) (6) >
Sent: Wednesday, April 15, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >
Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bright, Rick < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >; Corey, Larry < (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) >; Dolsten, Mikael < (b) (6) >; Erbeling, Emily (NIH/NIAID) [E] < (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Frankowski, David < (b) (6) >; Hudson, Thomas < (b) (6) >; James, Stephanie (FNIH) [T] < (b) (6) >; Klock, Kevin (FNIH) [T] < (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) >; Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) >; Mascola, John < (b) (6) > Meeker, David < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) > Pangalos, Mene < (b) (6) > Pao, William < (b) (6) > Paul, Steve < (b) (6) >; Perlmutter, Roger < (b) (6) > Plump, Andy < (b) (6) >; Rasi, Guido < (b) (6) >; Reed, John < (b) (6) >; Rouse,

Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel
 (b) (6) : Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Tsai, John
 (b) (6) : Vessey, Rupert (b) (6) Virgin, Skip (b) (6) >; Wholley, David
 (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER) < (b) (6) >; Young, John
 < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) >; Bascles, Lionel
 (b) (6) Cohen, Myron < (b) (6) Corey, Larry (b) (6) :
 Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C] (b) (6) :
 Doroshov, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] < (b) (6) : Heaton,
 Penny < (b) (6) King, James (b) (6) >; Kurilla, Mike <mk486x@nih.gov>; Nayak,
 Seema (NIH/NIAID) [E] (b) (6) : Parker, Ashley (NIH/OD) [E] < (b) (6) : Payton, Manzine
 (b) (6) >; Resnansky, Laura (b) (6) >; Srinivasan, Badhri
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) : Tountas, Karen (FNIH) [T]
 (b) (6) >; Vincent, Mike (b) (6) >; Wachtel, Jonathan (b) (6)
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bozzette,
 Sam (NIH/NCATS) [E] (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6) >;
 Butters, Joan (b) (6) >; De Claro, R. Angelo (FDA/CDER) (b) (6) >;
 Draghia-Akli, Ruxandra < (b) (6) : Eisner, Mark < (b) (6) Gottesdiener, Keith
 (b) (6) : Hughes, Eric (b) (6) : Judy Currier
 < (b) (6) Kim, Elizabeth (b) (6) >; LaVange, Lisa (b) (6) >; Levy, Elliot
 (b) (6) >; Mellors, John < (b) (6) Menon, Sandeep < (b) (6) Parker,
 Ashley (NIH/OD) [E] (b) (6) >; Patel, Naimish < (b) (6) Peppercorn, Amanda
 (b) (6) >; Poole, Mike (b) (6) >; Prosch, Michael
 < (b) (6) gov>; Read, Sarah (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) : Shen,
 Yuan Li (FDA/CDER) (b) (6) : Stein, Peter (FDA/CDER) (b) (6) >; Adams, Peter
 (OS/ASPR/BARDA) < (b) (6) >; Alvarez, Rosa (b) (6) >; Anderson, Annaliesa
 (b) (6) : Baric, Ralph (b) (6) : Carter, Kara (b) (6) :
 Colvis, Christine (b) (6) : Deming, Damon (FDA/CDER) < (b) (6) : Diamond,
 Michael (b) (6) >; Duncan, Ken (b) (6) >; Fernandes, Prabhavathi
 (b) (6) >; Gatto, Greg (b) (6) Grobler, Jay (b) (6) : Hewitt, Judith
 (b) (6) >; Jonson, Samantha (NIH/NCATS) [E] (b) (6) : Lutz, Cat < (b) (6) :
 Menetski, Joseph (FNIH) [T] < (b) (6) Nestle, Frank (b) (6) >; Ottinger, Liz
 (b) (6) : Parker, Ashley (NIH/OD) [E] (b) (6) >; Payne, David
 < (b) (6) Rappaport, Jay (b) (6) >; Stegmeier, Frank <fs (b) (6) :
 Young, John < (b) (6) : Annunziato, Paula (b) (6) : Arvin, Ann
 (b) (6) : Buchbinder, Susan (b) (6) : Corey, Larry < (b) (6) >;
 Davis, Mark < (b) (6) : Emini, Emilio < (b) (6) : Hanon, Emmanuel
 < (b) (6) : Haynes, Barton < (b) (6) : Hotez, Peter < (b) (6) : Jansen,
 Kathrin (b) (6) : Lanzavecchia, Antonio (b) (6) : Lowy, Douglas (NIH/NCI) [E]
 < (b) (6) : Marks, Peter (FDA/CDER) (b) (6) >; Mascola, John (NIH/VRC) [E]
 < (b) (6) : Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Offit, Paul
 (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Santos, Nancy < (b) (6) :
 Schuitemaker, Hanneke < (b) (6) : Tartaglia, Jim < (b) (6) : Tolman, Brett
 (b) (6) (b) (6) (b) (6)

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 8/18/2020 2:23:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6)]; Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Pao, William [(b) (6) Plump, Andrew [(b) (6) Stoffels, Paul (b) (6) ; Woodcock, Janet (FDA/CDER) [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John (b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [(b) (6)]
CC: Anderson, James (NIH/OD) [E] [(b) (6)]; Austin, Christopher (NIH/NCATS) [E] [(b) (6)]; Burklow, John (NIH/OD) [E] [(b) (6) .gov]; Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6)]; FNIH Central Account [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)]; Carver, Trea (NIH) [C] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Tajalli, Ada (NIH/OD) [E] [(b) (6)]; Lucas Smalldon [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]
Subject: ACTIV EC & Working Group Co-Chair Meeting
Location: [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))
Start: 9/9/2020 6:30:00 PM
End: 9/9/2020 7:30:00 PM
Show Time As: Free

Required Attendees: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 7/30/2020 3:22:36 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Just curious how many patients they are talking about doing DNA analysis. GWAS doesn't really work with small numbers.

Francis

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, July 29, 2020 11:05 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Hi Team,

I just confirmed with the ACTIV-3 team they will be testing a subset of the patients from ACTIV-3, but it will be done under a separate protocol called INSIGHT 004 that is open at certain sites where the trial will be activated.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Wednesday, July 29, 2020 9:53 PM
To: Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Anderson, James (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6)
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Stacey said there is collection of samples for genetic characterization in ACTIV-3. Copying her for clarification.

From: Lane, Cliff (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, July 29, 2020 6:20 PM
To: Wholley, David (FNIH) [T] (b) (6) >; Collins, Francis (NIH/OD) [E] <(b) (6)> >; Freire, Maria

COLL0000019964-2515395

(FNIH) [T] (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Anderson, James (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >

Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

I am not aware of plans to do any genomics in ACTIV-3 as written. My guess it a similar situation for ACTIV-2. One could do amendments to add genomics but I am not advocating that approach given the time/complexity it would add. As noted, we have large observational cohort studies looking at genomics. I think it is something we could ask Team 2 to evaluate in the context of the treatment studies.

Cliff

From: "Wholley, David (FNIH) [T]" (b) (6)
Date: Wednesday, July 29, 2020 at 5:58 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)>, "Freire, Maria (FNIH) [T]" (b) (6), "Austin, Christopher (NIH/NCATS) [E]" <aust(b) (6)>, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, Lawrence Tabak <(b) (6)>, "Anderson, James (NIH/OD) [E]" <(b) (6)>, "Parker, Ashley (NIH/OD) [E]" (b) (6) >
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Francis, I composed the following reply to Robert for your consideration. I'm happy to send it (he wrote to both of us) or you can; feel free to edit of course in either case. Cliff, please weigh in on how I have characterized the NIAID study you mentioned this morning. Thanks

Hi Robert:

Point taken. As always, we have to balance the benefits associated with genetic testing vs. the burden on sites of collection and banking and the need to make sure our trials are progressing as rapidly as possible. ACTIV-3 and ACTIV-4 are indeed planning to collect material for genetic testing from a reasonable subset of participants. ACTIV-1 does not have that in plan at this point, but may be willing to consider a substudy at more high functioning sites. This would be a hard sell for ACTIV-2, of course, as it is an outpatient cohort. FYI, NIAID is also planning a fairly large observational study that will include genetic analysis. Please let me know if you have other thoughts.

Regards,
David

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, July 29, 2020 7:43 AM
To: Freire, Maria (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Anderson, James (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: FW: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

From: Plenge, Robert (b) (6)
Sent: Wednesday, July 29, 2020 7:33 AM
To: Wholley, David (FNIH) [T] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data ([here](#), [here](#), [here](#), [here](#)), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From: "Melencio, Cheryl (FNIH) [T]" <(b) (6)> on behalf of "Wholley, David (FNIH) [T]" <(b) (6)>

Date: Tuesday, July 28, 2020 at 10:55 PM

To: "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)>, "Bancel, Stephane" <(b) (6)>, "Carter, Kara" <(b) (6)> "Cavaleri, Marco" <(b) (6)>, "Cihlar, Tomas" <(b) (6)>, "Collins, Francis (NIH/OD) [E]" <(b) (6)>, "Corey, Larry" <(b) (6)>, "Culp, Michelle (NIH/OD) [E]" <(b) (6)>, "Disbrow, Gary (OS/ASPR/BARDA)" <(b) (6)> "Dolsten, Mikael" <(b) (6)> "Erbelding, Emily (NIH/NIAID) [E]" <(b) (6)>, "Erck, Stan" <(b) (6)> "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Freire, Maria (FNIH) [T]" <(b) (6)> "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)>, "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)>, "Hudson, Thomas" <(b) (6)>, "James, Stephanie (FNIH) [T]" <(b) (6)> "Johnson, Robert (OS/ASPR/BARDA)" <(b) (6)> "Kramer, Lynn" <(b) (6)>, "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>, "Lepore, John" <(b) (6)>, "Marks, Peter (FDA/CBER)" <(b) (6)>, "Marston, Hilary (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <jmasco (b) (6)> "Meeker, David" <(b) (6)>, "Menetski, Joseph (FNIH) [T]" <(b) (6)> "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" <(b) (6)> "Pandya, Hitesh" <(b) (6)> "Pangalos, Mene" <(b) (6)>, "Pao, William" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)>, "Paul, Steve" <(b) (6)>, "Perlmutter, Roger" <(b) (6)>, "Plenge, Robert" <(b) (6)> "Plump, Andy" <(b) (6)> Rachel Ramoni <(b) (6)> "Rasi, Guido" <(b) (6)> "Reed, John" <(b) (6)> "Reese, David" <(b) (6)> "Rouse, Doris" <(b) (6)>, "Santos, Michael (FNIH) [T]" <(b) (6)>, "Skovronsky, Daniel" <(b) (6)> "Stein, Peter (FDA/CDER)" <(b) (6)>, "Stoffels, Paul" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)>, "Talley, Michael" <(b) (6)>, "Tsai, John" <(b) (6)> "Vessey, Rupert" <(b) (6)> "Virgin, Skip" <(b) (6)>, "Wholley, David (FNIH) [T]" <(b) (6)> "Woodcock, Janet (FDA/CDER)" <(b) (6)>, "Young, John" <(b) (6)>, "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)>, "Desrosiers, Betsy" <(b) (6)>, Eric Hughes <(b) (6)> "Jansen, Kathrin" <(b) (6)> "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)>, "Lowy, Douglas (NCI)" <(b) (6)> Read, Sarah (NIH/NIAID) [E]" <(b) (6)> "Young, John" <(b) (6)> (b) (6)

Cc: "Bianchi, Diana (NIH/NICHD) [E]" <(b) (6)> "Byrnes, Noni (NIH/CSR) [E]" <(b) (6)>, "Glass, Roger (NIH/FIC) [E]" <(b) (6)>, "Hodes, Richard (NIH/NIA) [E]" <(b) (6)> "Koob, George (NIH/NIAAA) [E]" <(b) (6)> "Koroshetz, Walter (NIH/NINDS) [E]" <(b) (6)>, "Langevin, Helene (NIH/NCCIH) [E]" <(b) (6)>, "Norris, Andrea (NIH/CIT) [E]" <andrea (b) (6)> "Perez-Stable, Eliseo (NIH/NIMHD) [E]" <(b) (6)>, "Rodgers, Griffin (NIH/NIDDK) [E]" <(b) (6)>, "Schwetz, Tara (NIH/OD) [E]" <(b) (6)>, "Sharpless, Norman (NIH/NCI) [E]" <(b) (6)> "Tucci, Debara (NIH/NIDCD) [E]" <(b) (6)> "Tumminia, Santa (NIH/NEI) [E]" <(b) (6)>, "Volkow, Nora (NIH/NIDA) [E]" <(b) (6)> "Woychik, Rick (NIH/NIHES) [E]" <(b) (6)>, "Adam, Stacey (FNIH) [T]" <(b) (6)> "Alvarez, Rosa" <(b) (6)> "Anderson, Margaret" <(b) (6)>

(b) (6) >, "Chen, Helen" < (b) (6) "Elsaid, Olivia"
(b) (6) , "Gonzalez, Nina" (b) (6) "James, Stephanie (FNIH) [T]"
(b) (6) , "Menetski, Joseph (FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]"
< (b) (6) "Stratton, Ben" (b) (6) >, "Tolman, Brett" (b) (6)
"Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan" < (b) (6) "Wholley,
David (FNIH) [T]" (b) (6) >, "Anderson, James (NIH/OD) [E]" < (b) (6)
"Burklow, John (NIH/OD) [E]" < (b) (6) "Castillejos, Carlos" < (b) (6) "Culp,
Michelle (NIH/OD) [E]" (b) (6) >, FNIH Central Account (b) (6) "Freire,
Maria (FNIH) [T]" (b) (6) "Gadbois, Ellen (NIH/OD) [E]" (b) (6) "Wolinetz,
Carrie (NIH/OD) [E]" (b) (6) >, "Burklow, John (NIH/OD) [E]" (b) (6)
"Gorman, Greta (FNIH) [T]" < (b) (6) "Hallett, Adrienne (NIH/OD) [E]"
< (b) (6) "Meltzer, Abbey (FNIH) [T]" (b) (6) >, "Myles, Renate (NIH/OD) [E]"
(b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6)

Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Resent-From: (b) (6)

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/23/2020 3:48:10 AM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; (b) (6) Gelijns, Annetine [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; Thompson, Taylor, M.D. [(b) (6)]; Babiker, Ab [(b) (6)]; Ginde, Adit [(b) (6)]; Aileen M Ilaria [(b) (6)]
CC: Chen, Helen Q. [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [(b) (6)]; Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccb]; Eileen Denning [(b) (6)]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Engel, Theresa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e86305ea82754e65b67a63591ed867ba-engelt]; Lisbeth Jørgensen [(b) (6)]; RH-FP-INSIGHT014-ACTIV3 [insight014-activ3.rigshospitalet@regionh.dk]; Erhardt, William (HHS/IOS) [(b) (6)]; Judith Anne Gallagher [(b) (6)]

Subject: ACTIV-3 Operations Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Operations Team Meeting Agenda_20200623.pdf
Location: <https://fnih.zoom.us/j> (b) (6)

Start: 6/23/2020 3:00:00 PM
End: 6/23/2020 4:00:00 PM
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Required Attendees: Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR); Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab; Ginde, Adit; Aileen M Ilaria

Optional Attendees: Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning; Baseler, Beth (NIH) [C]; Engel, Theresa (NIH) [C]; Lisbeth Jørgensen; RH-FP-INSIGHT014-ACTIV3; Erhardt, William (HHS/IOS); Judith Anne Gallagher

Dear ACTIV-3 Operations Team,

Please find attached the high level agenda for tomorrow. Let me know if you have any additions or amendments.

Thanks,
Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/17/2020 7:55:15 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas (b) (6) ; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lee, William [(b) (6) Lepore, John (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William (b) (6)) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John (b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [john. (b) (6) Vessey, Rupert [(b) (6) m]; Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

[(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin
 (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
 CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa
 [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen
 [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Ben
 [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
 (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly
 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan
 [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6)
 Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide
 [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; McManus, Ayanna
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth
 [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann
 [(b) (6) Riccobene, Kim [(b) (6) Sepulveda, Dorina (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
 [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Anderson, James (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Hallett, Adrienne (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Hardesty, Rebecca
 (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Gorman, Greta (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Togashi, Mieko (NIH/NCI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
[(b) (6) Zottoli, Jessica | (b) (6)

Subject: ACTIV Leadership Call #6

Location: <https://fnih.zoom.us/> (b) (6)

Start: 7/29/2020 6:30:00 PM

End: 7/29/2020 8:00:00 PM

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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lee, William; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/14/2020 1:24:31 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin (b) (6) ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6)
Subject: ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting
Location: <https://zoom.us/> (b) (6)
Start: 4/15/2020 5:30:00 PM
End: 4/15/2020 6:30:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; R. Angelo Declaro; Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you for your interest and participation in the Master Protocol sub-group. We are appreciative of your time and look forward to a focused discussion on the development of COVID-19 Master Protocols.

Our first meeting will take place today, Wednesday April 15th from 1:30pm-2:30pm ET. Dial-in instructions are below, similar to the zoom call on Monday. We wanted to notify you promptly of the meeting time and will follow up with an agenda and any necessary materials prior to the call.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6)

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(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6)]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];

(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas

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CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Stratton, Benjamin [(b) (6) Diamond, Michael [(b) (6) Rodriguez, Robin D [(b) (6)

Start: 5/12/2020 6:00:00 PM
End: 5/12/2020 7:00:00 PM

Recurrence: (none)

From: (b) (6) [(b) (6)]
Sent: 8/18/2020 3:07:25 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Fwd: Notes from Friday's ACTIV Executive Committee & Working Group Co-chair Call
Attachments: image001.png; ATT00001.htm; 2020-08-14_Executive_Committee_Meeting_Summary vFinal.docx; ATT00002.htm

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" < (b) (6) >
Date: August 18, 2020 at 9:16:02 AM EDT
To: "Collins, Francis (NIH/OD) [E]" < (b) (6) > "Disbrow, Gary (OS/ASPR/BARDA)" < (b) (6) > "Dolsten, Mikael" < (b) (6) > "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) > "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) > "Marks, Peter (FDA/CBER)" < (b) (6) > "Pao, William" < (b) (6) > "Plump, Andrew" < (b) (6) > "Stoffels, Paul" < (b) (6) > "Woodcock, Janet (FDA/CDER)" < (b) (6) > "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) > "Desrosiers, Betsy" < (b) (6) > Eric Hughes < (b) (6) > "Jansen, Kathrin" < (b) (6) > "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) > "Lowy, Douglas (NCI)" < (b) (6) > "Read, Sarah (NIH/NIAID) [E]" < (b) (6) > "Young, John" < (b) (6) >
Cc: "Adam, Stacey (FNIH) [T]" < (b) (6) > "Alvarez, Rosa" < (b) (6) > "Anderson, Margaret" < (b) (6) > "Chen, Helen" < (b) (6) > "Elsaid, Olivia" < (b) (6) > "Gonzalez, Nina" < (b) (6) > "Hawk, Harrison" < (b) (6) > "Menetski, Joseph (FNIH) [T]" < (b) (6) > "Santos, Michael (FNIH) [T]" < (b) (6) > "Stratton, Benjamin" < (b) (6) > "Tolman, Brett" < (b) (6) > "Tountas, Karen (FNIH) [T]" < (b) (6) > "Wachtel, Jonathan" < (b) (6) > "Wholley, David (FNIH) [T]" < (b) (6) > "Anderson, James (NIH/OD) [E]" < (b) (6) > "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) > "Burklow, John (NIH/OD) [E]" < (b) (6) > "Castillejos, Carlos" < (b) (6) > "Culp, Michelle (NIH/OD) [E]" < (b) (6) > FNIH Central Account < (b) (6) > "Freire, Maria (FNIH) [T]" < (b) (6) > "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) > "Hallett, Adrienne (NIH/OD) [E]" < (b) (6) > "Lane, Cliff (NIH/NIAID) [E]" < (b) (6) > "Myles, Renate (NIH/OD) [E]" < (b) (6) > "Parker, Ashley (NIH/OD) [E]" < (b) (6) > "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) > "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6) > "Melencio, Cheryl (FNIH) [T]" < (b) (6) >
Subject: Notes from Friday's ACTIV Executive Committee & Working Group Co-chair Call

Dear ACTIV Executive Committee Members and meeting attendees:

Please find attached the notes from our Friday, August 14 ACTIV Executive Committee meeting. As always, please email me with any concerns, questions, or additional comments.

Regards,
David

David Wholley
Senior Vice President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/3/2020 6:30:39 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [(b) (6)]; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx
Location: <https://fnih.zoom.us/> [(b) (6)]
Start: 5/3/2020 7:00:00 PM
End: 5/3/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [(b) (6)]

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet with multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

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From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/21/2020 10:23:31 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Wachtel, Jonathan [(b) (6)] Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveesson, Nancy
 [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: CTC WG call #11 agenda and ACTIV protocol tracker

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf

Dear Colleagues,

Attached is the Agenda for the next Clinical Trial Capacity WG meeting, scheduled for tomorrow, Friday May 22, at 9 am eastern US time. Please note that we will be hearing from the All of Us program and how they might be useful for implementing ACTIV protocols.

In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future.

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
(b) (6) | fnih.org
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US
US
US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/j/> (b) (6)

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 9/9/2020 5:49:05 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Did you figure out how to make hover over work in a PDF?
The PPTX file is working fine.

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, September 9, 2020 1:45 PM
To: George, Jill (NIH/OD) [E] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Jill and Lauren,

The clinical trial matrix is out for review by the ACTIV Tx working group.

Jill -- Helen shared the attached PDF and I noticed the hover over does not work. I am not concerned about this issue given it's the WG reviewing but wanted to flag in case something needs to be tweaked in the PP file attached for future sharing using PDF.

Thanks,
Ashley

-----Original Message-----

From: Chen, Helen Q. <(b) (6)>
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>;
Butterton, Joan <(b) (6)> >; De Claro, R. Angelo (FDA/CDER) <(b) (6)>.gov>;
Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith
<(b) (6)> Eric Hughes <(b) (6)> Judy Currier
<(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)>
Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish
<(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> >; Read, Sarah
(NIH/NIAID) [E] <(b) (6)> >; Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li
(FDA/CDER) <(b) (6)> >; Stein, Peter (FDA/CDER) <(b) (6)> >; Wholley, David
(FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva
(FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)> Garner, Carl
<(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Koroshetz, Walter
(NIH/NINDS) [E] <(b) (6)> Timothy Burgess <(b) (6)> Reineck, Lora
(NIH/NHLBI) [E] <(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)>
Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E]
<(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Culb. Michelle (NIH/OD) [E] <(b) (6)> >; Jacqueline Kirchner
<(b) (6)> Beidel, John (NIH) [E] <(b) (6)> Phillips, L
Revell CIV DTRA RD (USA) <(b) (6)> Petrovick, Martha - 0449 - MITLL
<(b) (6)> Sizemore, Christine (NIH/FIC) [E]
<(b) (6)>
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
<(b) (6)> Jansen, Kathryn <(b) (6)> Kurilla, Michael
(NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John
<(b) (6)> Briggs, Mary <(b) (6)> Butcher, Tina <(b) (6)>
Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Salathin, Carla <(b) (6)> >; Tountas, Karen (FNIH) [T]
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Wachtel, Jonathan <(b) (6)> btolman <(b) (6)> Alvarez,
Rosa Maria <(b) (6)> Gonzalez, Nina <(b) (6)> Dana Carluccio
<(b) (6)> Rose Li Central Account <(b) (6)> Margaret
Anderson <(b) (6)> Lucas Smalldon <(b) (6)> Stratton,
Benjamin <(b) (6)> Mollica, Linda /US
<(b) (6)> >; Oashu, Felicia (NIH/OD) [E] <(b) (6)> >; Patterson, Amy
(NIH/NHLBI) [E] <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Marston,
Hilary (NIH/NIAID) [E] <(b) (6)> >; Wung, Peter /US <(b) (6)> Hoots, W. Keith
(NIH/NHLBI) [E] <(b) (6)> Groesch, Mary (NIH/NHLBI) [E] <(b) (6)> >; Shipp,

Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
< (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6)
Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Freire, Maria (FNIH)
[T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butters, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Prosch, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L. Revel CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Maccone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/> (b) (6)

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Sent: 5/11/2020 10:50:52 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c289105913411a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Smith, David [(b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; (b) (6) Eron, Joe [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Ghosh, Pranab [(b) (6) Le Corre, Christophe [(b) (6)]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Eron, Joseph J Jr [(b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]
Subject: Follow-up from ACTIV TX-Clinical Master Protocol Subgroup #15
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 11May2020_Key Takeaways.pdf; ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf

Dear TX-Clinical Master Protocol Subgroup,

Thank you all for a great call today and giving us an extra 30 minutes more than usual to allow us to hear the presentation from the ACTG group on their outpatient master protocol.

We also want to say huge thank you to Sandeep, Pranab, and Christophe for the very good and very fast simulation work that they put together for ACTT-3. All the pieces for our first trial are falling into place.

Please find attached a brief summary of the discussion and the slides once again to refer to for both the ACTT-3 progress and the ACTG study. Please keep in mind that both of these studies are pre-FDA review so we would ask that the details not be shared broadly at this time.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 12:53:43 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6) .gov]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [(b) (6)]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)]; Carlos O Garner [(b) (6)]; Goff, David (NIH/NHLBI) [E] [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6)]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [(b) (6)]; Melencio, Cheryl (FNIH) [T] [(b) (6)]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Ward, Jackie (NIH/NINDS) [E] [(b) (6)]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8
Attachments: ACTIV Therapeutics-Clinical_AP Subgroup_7May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 07May2020 Agenda.pdf
Location: <https://fnih.zoom.us/> [(b) (6)]
Start: 5/7/2020 5:00:00 PM
End: 5/7/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [(b) (6)]

Dear TX-Clinical Agent Prioritization Subgroup,

We are looking forward to our meeting tomorrow during which we will work to flesh out some of our suggestions for improvements in the prioritization process a bit more. We will also talk about next steps over the rest of this week and next.

Please find attached the agenda and slides for tomorrow's meeting. If you have any additions or amendments, please let me know.

Thanks,
Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/17/2021 8:22:54 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Dolsten, Mikael [(b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Venkayya, Rajeev [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) John Lepore (b) (6) Grant, Sarah
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Helen [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah
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Nicole (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Mendelson, Jesse (b) (6) Menetski, Joseph (FNIH) [T]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Wholley, David
(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Castillejos, Carlos (b) (6) Culp, Michelle (NIH/OD) [E]
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(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne
(NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, March 18, 2021
Attachments: 03.18.21 ACTIV EC and Leadership Team Meeting 20210317_vFinal.pdf; 03.18.21 ACTIV EC and Leadership Team Meeting_APPENDIX_20210317_vF.pdf; 2021-02-17_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Thursday, March 18, 2021 from 10:30 a.m. to 12:00 p.m. Eastern U.S. Time.** The minutes from the February 17 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/9/2020 12:21:37 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: GSK follow up on FNIH COVID call

I'll do it.

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Wednesday, April 8, 2020 7:36 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Subject: FW: GSK follow up on FNIH COVID call

FYI We'll add them to the list. Francis, do you want to send out the invitation emails? We can forward yours if you don't have time.

From: John Lepore (b) (6)
Sent: Wednesday, April 8, 2020 5:55 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Santos, Michael (FNIH) [T] <(b) (6)>; David Payne (b) (6) <(b) (6)>; Emmanuel Hanon (b) (6) <(b) (6)>; Amanda Peppercorn (b) (6) <(b) (6)>
Subject: RE: GSK follow up on FNIH COVID call

Hi David -

Writing e-mail to you as I received this...

Yes, we are very keen to participate with the following suggestions:

- **David Payne**, head of our infectious disease research group, to participate on the preclinical workstream. David is an industry veteran with extensive drug discovery experience across novel anti-bacterials and anti-virals and I think can contribute importantly to discussions about optimizing assays, reagents and models.
- **Amanda Peppercorn**, physician-scientist with extensive experience in clinical trials and and regulatory interactions for anti-viral drug-development; has led our influenza program, among others. To participate on the clinical trials workstream.

- **Emmanuel Hanon** - head of vaccines R&D in GSK, to participate on the vaccines workstream.

I've copied all 3 on this e-mail so you can contact them directly.

If you would please keep me copied in to minutes from the various workstreams, I'd really appreciate that.

If there is anything else GSK could help with, please do reach out.

Thanks so much for your help -

John

From: Wholley, David (FNIH) [T] (b) (6)

Sent: Wednesday, April 08, 2020 5:48 PM

To: John Lepore (b) (6)

Cc: Santos, Michael (FNIH) [T] < (b) (6)>

Subject: RE: GSK follow up on FNIH COVID call

EXTERNAL

Hi John, I don't think I have seen your suggestions for the COVID committees yet, just checking. We'd love to have input from your leadership, particularly on vaccines and therapeutics groups. Thanks, David

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

From: Eron, Joseph J Jr [(b) (6)]
Sent: 5/28/2020 6:45:14 PM
To: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes (b) (6) LaVange, Lisa M [(b) (6)] Sandeep Menon (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proschan]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)] (b) (6) (b) (6) (b) (6)
(t (b) (6) Wohl, David A [(b) (6)] Fischer, William A. II [(b) (6)] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [(b) (6)] Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest (b) (6) ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [(b) (6)] Smith, David [(b) (6)] Paul Klekotka [klekotka_paul@lilly.com]; Ajay Nirula [(b) (6)] Lucas Smalldon [(b) (6)] Rose Li Central Account [(b) (6)] Dana Carluccio [dana.carluccio@roseliassociates.com]; Chen, Helen Q. [(b) (6)]
Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

I was referring to the paper and its implications for infectiousness
I think development of a quantitative assay with internal standards that will allow for more precise quantitation beyond just cycle number which might vary between assay runs is the way to go.

Joseph J. Eron MD
Professor of Medicine
Chief, Infectious Diseases Division
(b) (6)

Admin: (b) (6)

From: Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) >

Sent: Thursday, May 28, 2020 2:41 PM

To: Eron, Joseph J Jr < (b) (6) > Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M < (b) (6) > Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER) < (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Farley, John (FDA/CDER) < (b) (6) > Karen Lynn Price < (b) (6) > Wohl, David A < (b) (6) > Fischer, William A. II < (b) (6) > Javan, Arzhang (NIH/NIAID) [C] < (b) (6) > Roa, Johanna < (b) (6) > Kim, Peter (NIH/NIAID) [E] < (b) (6) > Butterson, Joan < (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) > Woodcock, Janet (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Carlos O Garner < (b) (6) > Bugin, Kevin (FDA/CDER) < (b) (6) > Kozak, Marina (OS/ASPR/BARDA) < (b) (6) >

Cc: DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan < (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/NCI) [F] < (b) (6) > Johanna Roa < (b) (6) > Smith, David < (b) (6) > Paul Klekotka < (b) (6) > Ajay Nirula < (b) (6) > Lucas Smalldon < (b) (6) > Rose Li Central Account < (b) (6) > Dana Carluccio < (b) (6) > Chen, Helen Q. < (b) (6) >

Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

Thanks Joe

Cycle thresholds will be important to specify I would suggest. Amplifying non-infectious fragments vs correlating with what would suggest infectious virus begs for at least standardization of Ct. Or am I missing your point that we shouldn't bother with setting Ct...as long as it can be amplified no matter how many cycles, it would still be a positive? CDC colleagues may have more on this issue.

Lynn

From: Eron, Joseph J Jr < (b) (6) >) (6)

Sent: Thursday, May 28, 2020 12:25 PM

To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M < (b) (6) > Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER) < (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Farley, John (FDA/CDER) < (b) (6) > Karen Lynn Price < (b) (6) > Wohl, David A < (b) (6) > Fischer, William A. II < (b) (6) > Javan, Arzhang (NIH/NIAID) [C] < (b) (6) > Roa, Johanna < (b) (6) > Kim, Peter (NIH/NIAID) [E] < (b) (6) > Butterson, Joan < (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) > Woodcock, Janet (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Carlos O Garner < (b) (6) > Bugin, Kevin (FDA/CDER) < (b) (6) > Marks, Gilbert (OS/ASPR/BARDA)

(CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA) < (b) (6)
Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
< (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/NCI) [F] < (b) (6)
Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
(b) (6)) (6) Ajay Nirula (b) (6) 5) Lucas Smalldon
< (b) (6) Rose Li Central Account < (b) (6) Dana Carluccio
< (b) (6) Chen, Helen Q. < (b) (6)

Subject: Re: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

I don't find this particularly reassuring. As you know it is extremely difficult to culture HIV from semen but there is no doubt about its infectiousness

Joseph Eron MD
Professor of Medicine
Division of Infectious Disease
UNC Chapel Hill
(b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >
Sent: Thursday, May 28, 2020 11:45:50 AM
To: Adam, Stacey (FNIH) [T] < (b) (6) > Judy Currier < (b) (6) > Eric Hughes
< (b) (6) > LaVange, Lisa M < (b) (6) > Sandeep Menon
< (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah
(NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER) < (b) (6) > Rubin, Daniel B.
(FDA/CDER) < (b) (6) > Farley, John (FDA/CDER) < (b) (6) > Karen Lynn Price
(b) (6) (b) (6) (b) (6) < (b) (6) > (b) (6)
< (b) (6) > (b) (6) < (b) (6) > (b) (6)
< (b) (6) > Wohl, David A (b) (6) > Fischer, William A. II
(b) (6) > Eron, Joseph J Jr (b) (6) > Javan, Arzhang (NIH/NIAID) [E]
< (b) (6) > Roa, Jhoanna < (b) (6) > (b) (6) < (b) (6) > Kim, Peter (NIH/NIAID)
[E] < (b) (6) > Butters, Joan <joan (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E]
< (b) (6) > Woodcock, Janet (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER)
< (b) (6) > Carlos O Garner (b) (6) (b) (6) > Bugin, Kevin (FDA/CDER)
< (b) (6) > Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) > Kozak, Marina
(OS/ASPR/BARDA) < (b) (6) >
Cc: DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan
< (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Jhoanna Roa < (b) (6) > Eron, Joseph J Jr (b) (6) (b) (6) > Smith, David
< (b) (6) > Paul Klekotka (b) (6)) (6) > Ajay Nirula (b) (6) (b) (6) > Lucas
Smalldon < (b) (6) > Rose Li Central Account < (b) (6) > Dana
Carluccio < (b) (6) > Chen, Helen Q. < (b) (6) >
Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

Of interest re interpreting virology - <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa638/5842165>

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Saturday, May 23, 2020 1:02 PM
To: Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; LaVange, Lisa M; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;
(b) (6) Kim, Peter (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butters, Joan; Higgs, Elizabeth
(NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER);
Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dana Carluccio;
Chen, Helen Q.

Subject: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

When: Wednesday, May 27, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,
Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/15/2020 5:38:22 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: FW: ACTIV Vaccines Working Group meeting
Location: Webex: <https://nih.webex.co> (b) (6)
Start: 7/29/2020 2:00:00 PM
End: 7/29/2020 3:00:00 PM
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-----Original Appointment-----

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Tuesday, June 30, 2020 3:18 PM
To: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; Arvin, Ann; Beth Bell (b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; Seals, Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks; (b) (6) (b) (6)
Cc: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; 'Wachtel, Jonathan'; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Arvin, Ann; Young, John
Subject: ACTIV Vaccines Working Group meeting
When: Wednesday, July 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Webex: <https://nih.webex.com/> (b) (6)

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Start: 7/15/2020 2:00:00 PM
End: 7/15/2020 3:00:00 PM

Recurrence: (none)

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/27/2020 3:42:28 AM
To: (b) (6) (b) (6) Jim.Tartagl (b) (6) (b) (6)
Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; (b) (6)
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Bett, Andrew J [(b) (6)
Gilbert PhD, Peter B [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Greg Glenn [(b) (6) Cavaleri Marco [(b) (6)
CC: (b) (6) (b) (6) (b) (6) Jeneffer Haynes
(b) (6) Tolman, Brett [(b) (6) Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brian Rosen [(b) (6) Cheryl Keech [(b) (6)
Subject: Agenda for the Protective Immune Responses Sub-Group meeting
Attachments: M_Cavaleri_regulatory_framework_emergencies.ppt

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

APAR0000006190-2515414

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/10/2020 12:21:23 AM
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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Eron, Joseph J Jr [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup #15
Location: https://fnih.zoom.us/ (b) (6)
Start: 5/11/2020 5:00:00 PM
End: 5/11/2020 6:30:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; (b) (6) Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/1/2020 1:33:24 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Gonzalez, Nina [(b) (6) Kim, Elizabeth [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group

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[(b) (6) Talley, Michael [(b) (6) Cavaleri, Marco
[(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange
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Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) [(b) (6)
CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Li, Rose [(b) (6) Zottoli, Jessica [(b) (6)
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Castillejos zenteno, Carlos [JRDUS] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Chen, Helen
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Dana Carluccio
[(b) (6)]

Subject: ACTIV Response Partnership Leadership Team Meeting #4

Attachments: Materials for June 3 ACTIV Partnership Leadership Call

Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/3/2020 4:00:00 PM

End: 6/3/2020 5:30:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; william.lee@gilead.com; Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio

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US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 7/8/2020 3:05:26 AM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy];
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell
(b) (6) [(b) (6) (b) (6) Cavalieri Marco
[(b) (6) (b) (6) (b) (6)
(b) (6) Greg Glenn [(b) (6) (b) (6) Haynes,
Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc], (b) (6)
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John
(NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy
(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email] (b) (6)
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) (b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
(b) (6) Jeneffer Haynes (b) (6) (b) (6)
(b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
(b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T]
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV
USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie
(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin [(b) (6) ; Anderson, Margaret
[(b) (6) (b) (6) (b) (6) Bethany Stokes
[(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH)
[(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Jacqueline Miller
[(b) (6) Kayvon Modjarrad [(b) (6)

Subject: Canceled: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.> (b) (6)

Start: 7/8/2020 5:15:00 PM

End: 7/8/2020 6:15:00 PM

Show Time As: Free

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
(b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) ; Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy,
Delia (DPH); Ann Arvin; Jacqueline Miller; Kayvon Modjarrad

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/8/2020 1:16:00 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Setup for Conference/Webex call re: monoclonal antibody combinatorial testing with Skip Virgin

Agree – one preclinical and one clinical WG member. Stacey and Joe please pick one of each and include them in the invitation? You will need to brief them on what this is all about of course.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Sunday, June 7, 2020 9:09 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Setup for Conference/Webex call re: monoclonal antibody combinatorial testing with Skip Virgin

I'd be fine with including one or two WG members – but that's probably enough. I'll count on you, Stacey, and David to figure out who that should be.

FC

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Sunday, June 7, 2020 9:06 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Cc: Wholley, David (FNIH) [T] (b) (6) (6) Adam, Stacey (FNIH) [T] (b) (6)
Subject: Setup for Conference/Webex call re: monoclonal antibody combinatorial testing with Skip Virgin

Dear Francis,

Do you want to have any of the working group experts on the call with Skip Virgin and Vir tomorrow? It seems like a lot of Vir folks, maybe they would be less forthcoming if we had others on the call.

I have not received any materials for this meeting.

Currently this is the invitee list.

Wholley, David (FNIH)
Collins, Francis (NIH/OD)
Woodcock, Janet (FDA/CDER)
Skip Virgin (Vir)
George Scangos (Vir)
Phil Pang (Vir)
Adam, Stacey (FNIH) [T]
Parker, Ashley (NIH/OD)
Graham, Barney (NIH/VRC)
Lane, Cliff (NIH/NIAID)
Menetski, Joseph (FNIH)

Joe

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Friday, June 5, 2020 6:44 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6); Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2:45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

Saturday call with J Kirchner:

Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)

Monday call with Skip Virgin:

Peter Adams, (OS/ASPR/BARDA); (b) (6)

COLL0000017753-2515418

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6)

John W Mellors at University of Pittsburgh; (b) (6)

Randall Tressler, (NIH/NIAID); (b) (6)

Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) | fnihi.org

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnihi.org/pandemic



From: Prabha Fernandes [(b) (6)]
Sent: 5/29/2020 7:42:01 PM
To: 'Kara Carter' [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a27ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [(b) (6) 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' [(b) (6)]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [(b) (6) 'Jansen, Kathrin' [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria'

[(b) (6) 'Kim, Elizabeth' [(b) (6) 'Tolman, Brett' [(b) (6) 'Wachtel, Jonathan' [(b) (6) 'Prabhavathi Fernandes' [(b) (6) 'Diamond, Michael' [(b) (6) 'Rose Li' [(b) (6) 'Dana Carluccio' [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D' [(b) (6) 'Dave Frankowski' [(b) (6) 'Baric, Toni C' [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Stratton, Benjamin' [(b) (6)

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Thx much Kara!

I just heard that it is being made and sold black market in China.

From: Kara Carter < (b) (6) >

Sent: Friday, May 29, 2020 3:40 PM

To: Prabha Fernandes < (b) (6) > 'Menetski, Joseph (FNIH) [T]' < (b) (6) >

< (b) (6) > (b) (6) (b) (6) 'Hild, Sheri (NIH/OD) [E]' < (b) (6) >

< (b) (6) > (b) (6) (b) (6) (b) (6) 'Baric, Ralph' < (b) (6) > 'Ottinger, Elizabeth (NIH/NCATS) [E]' < (b) (6) >

< (b) (6) > 'Colvis, Christine (NIH/NCATS) [E]' < (b) (6) > 'Hewitt, Judith (NIH/NIAID) [E]' < (b) (6) >

< (b) (6) > 'Deming, Damon (FDA/CDER)' < (b) (6) > (b) (6) (b) (6) 'Parker, Ashley (NIH/OD) [E]' < (b) (6) >

(b) (6) (b) (6) 'Adams, Peter (OS/ASPR/BARDA)' < (b) (6) > 'Rao, Srinivas' < (b) (6) >

< (b) (6) > 'Qashu, Felicia (NIH/OD) [E]' < (b) (6) > 'Tomas Cihlar' < (b) (6) >

< (b) (6) > 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' < (b) (6) >

Cc: 'Gadbois, Ellen (NIH/OD) [E]' < (b) (6) > 'Hughes, Eric' < (b) (6) > 'Gonzalez, Nina' < (b) (6) >

< (b) (6) > 'Cutillo, Christine (NIH/NCATS) [E]' < (b) (6) > 'Simon, Dina (NIH/OD) [C]' < (b) (6) >

< (b) (6) > 'Wholley, David (FNIH) [T]' < (b) (6) > 'Austin, Christopher (NIH/NCATS) [E]' < (b) (6) >

< (b) (6) > 'Melencio, Cheryl (FNIH) [T]' < (b) (6) > 'Colvis, Christine (NIH/NCATS) [E]' < (b) (6) >

< (b) (6) > 'Desrosiers, Betsy' < (b) (6) > 'Jansen, Kathrin' < (b) (6) >

< (b) (6) > 'Kurilla, Michael (NIH/NCATS) [E]' < (b) (6) > 'Lowy, Douglas (NCI)' < (b) (6) >

< (b) (6) > 'Read, Sarah (NIH/NIAID) [E]' < (b) (6) > 'Tountas, Karen (FNIH) [T]' < (b) (6) >

< (b) (6) > 'Santos, Michael (FNIH) [T]' < (b) (6) > 'Adam, Stacey (FNIH) [T]' < (b) (6) >

'James, Stephanie (FNIH) [T]' < (b) (6) > 'Alvarez, Rosa Maria' < (b) (6) > 'Kim, Elizabeth' < (b) (6) >

< (b) (6) > 'Tolman, Brett' < (b) (6) > 'Wachtel, Jonathan' < (b) (6) >

'Prabhavathi Fernandes' < (b) (6) > 'Diamond, Michael' < (b) (6) > 'Rose Li' < (b) (6) >

< (b) (6) > 'Dana Carluccio' < (b) (6) > 'Lagos, Enrique (NIH/NCATS) [E]' < (b) (6) >

< (b) (6) > 'Jonson, Samantha (NIH/NCATS) [E]' < (b) (6) > 'Burrus-Shaw, Cyndi (NIH/OD) [E]' < (b) (6) >

< (b) (6) > 'Rodriguez, Robin D' < (b) (6) > 'Dave Frankowski' < (b) (6) >

< (b) (6) > 'Baric, Toni C' < (b) (6) > 'Lowy, Douglas (NIH/NCI) [E]' < (b) (6) >

< (b) (6) > 'Florence, Clint (NIH/NIAID) [E]' < (b) (6) > 'Nancy Haigwood' < (b) (6) >

< (b) (6) > 'Stratton, Benjamin' < (b) (6) >

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

Kara



Kara Carter, PhD

Executive Vice President Infectious Disease

(b) (6)

www.evotec.com

From: Prabha Fernandes <(b) (6)>

Sent: Friday, May 29, 2020 3:31 PM

To: 'Menetski, Joseph (FNIH) [T]' <(b) (6)>

(b) (6) (b) (6) 'Hild, Sheri (NIH/OD) [E]' (b) (6);

(b) (6) Kara Carter <(b) (6)>

'Baric, Ralph' <(b) (6)> 'Ottinger, Elizabeth (NIH/NCATS [E])' <(b) (6)> 'Colvis, Christine (NIH/NCATS) [E]' <(b) (6)> 'Hewitt, Judith (NIH/NIAID) [E]' (b) (6) 'Deming, Damon (FDA/CDER)' (b) (6)

(b) (6) Parker, Ashley (NIH/OD) [E]' (b) (6)

'Adams, Peter (OS/ASPR/BARDA)' (b) (6); 'Rao, Srinivas' (b) (6); 'Qashu, Felicia (NIH/OD) [E]' (b) (6); 'Tomas Cihlar' (b) (6); 'Pitt, Margaret L CIV USARMY

MEDCOM USAMRIID (USA) (b) (6)

Cc: 'Gadbois, Ellen (NIH/OD) [E]' (b) (6) 'Hughes, Eric' (b) (6) 'Gonzalez, Nina' (b) (6); 'Cutillo, Christine (NIH/NCATS) [E]' (b) (6); 'Simon, Dina (NIH/OD) [C]' (b) (6); 'Wholley, David (FNIH) [T]' (b) (6); 'Austin, Christopher (NIH/NCATS) [E]' (b) (6); 'Melencio, Cheryl (FNIH) [T]' (b) (6); 'Colvis, Christine (NIH/NCATS) [E]' (b) (6); 'Desrosiers, Betsy' (b) (6); 'Jansen, Kathrin' (b) (6); 'Kurilla, Michael (NIH/NCATS) [E]' (b) (6); 'Lowy, Douglas (NCI)' (b) (6); 'Read, Sarah (NIH/NIAID) [E]' <(b) (6)> 'Tountas, Karen (FNIH) [T]' (b) (6); 'Santos, Michael (FNIH) [T]' (b) (6); 'Adam, Stacey (FNIH) [T]' (b) (6); 'James, Stephanie (FNIH) [T]' (b) (6); 'Alvarez, Rosa Maria' (b) (6); 'Kim, Elizabeth' (b) (6); 'Tolman, Brett' <(b) (6)> 'Wachtel, Jonathan' <(b) (6)> 'Prabhavathi Fernandes' <(b) (6)> 'Diamond, Michael' (b) (6); 'Rose Li' (b) (6); 'Dana Carluccio' <(b) (6)> 'Lagos, Enrique (NIH/NCATS) [E]' (b) (6); 'Jonson, Samantha (NIH/NCATS) [E]' (b) (6); 'Burrus-Shaw, Cyndi (NIH/OD) [E]' (b) (6); 'Rodriguez, Robin D' (b) (6); 'Dave Frankowski' (b) (6); 'Baric, Toni C' (b) (6); 'Lowy, Douglas (NIH/NCI) [E]' <(b) (6)> 'Florence, Clint (NIH/NIAID) [E]' <(b) (6)> 'Nancy Haigwood' (b) (6); 'Stratton, Benjamin' (b) (6)

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

[EXTERNAL]

Hi Joe,

When we prioritize re-purposed drugs..

APAR0000004839-2515419

Should we include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards,

Prabha

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Friday, May 29, 2020 3:25 PM
To: (b) (6); (b) (6); (b) (6); Hild, Sheri (NIH/OD) [E]
< (b) (6); (b) (6);
(b) (6); Baric, Ralph (b) (6); (b) (6); Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6); Colvis, Christine (NIH/NCATS) [E] (b) (6); >;
Hewitt, Judith (NIH/NIAID) [E] < (b) (6); Deming, Damon (FDA/CDER) < (b) (6);
(b) (6); (b) (6); Parker, Ashley (NIH/OD) [E]
(b) (6); Adams, Peter (OS/ASPR/BARDA)
< (b) (6); Rao, Srinivas (b) (6); >; Qashu, Felicia (NIH/OD) [E]
(b) (6); >; Tomas Cihlar (b) (6); Pitt, Margaret L CIV USARMY MEDCOM USAMRIID
(USA) < (b) (6);
Cc: Gadbois, Ellen (NIH/OD) [E] < (b) (6); Hughes, Eric < (b) (6); >; Gonzalez, Nina
(b) (6); >; Cutillo, Christine (NIH/NCATS) [E] (b) (6); >; Simon, Dina (NIH/OD) [C]
(b) (6); >; Wholley, David (FNIH) [T] (b) (6); Austin, Christopher (NIH/NCATS) [E]
(b) (6); >; Melencio, Cheryl (FNIH) [T] < (b) (6); Colvis, Christine (NIH/NCATS) [E]
(b) (6); Desrosiers, Betsy (b) (6); Jansen, Kathrin
(b) (6); Kurilla, Michael (NIH/NCATS) [E] (b) (6); Lowy, Douglas (NCI)
(b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); >; Tountas, Karen (FNIH) [T] (b) (6);
Santos, Michael (FNIH) [T] < (b) (6); Adam, Stacey (FNIH) [T] < (b) (6); James, Stephanie (FNIH)
[T] (b) (6); >; Alvarez, Rosa Maria < (b) (6); Kim, Elizabeth (b) (6); Tolman,
Brett < (b) (6); Wachtel, Jonathan < (b) (6); Prabhavathi Fernandes
< (b) (6); Diamond, Michael < (b) (6); Rose Li
(b) (6); >; Dana Carluccio (b) (6); >; Lagos, Enrique (NIH/NCATS) [E]
< (b) (6); Jonson, Samantha (NIH/NCATS) [E] < (b) (6); Burrus-Shaw, Cyndi
(NIH/OD) [E] (b) (6); (b) (6); Rodriguez, Robin D < (b) (6); Dave Frankowski
(b) (6); >; Baric, Toni C (b) (6); Lowy, Douglas (NIH/NCI) [E]
(b) (6); >; Florence, Clint (NIH/NIAID) [E] < (b) (6); >; Nancy Haigwood
< (b) (6); >; Stratton, Benjamin (b) (6)
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

APAR0000004839-2515419

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 1:50:00 AM
To: Eric Hughes [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)] Keith Gottesdiener [(b) (6)] Elliott Levy [(b) (6)] Wung, Peter /US [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [(b) (6)]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf; 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from yesterday's meeting.

In addition, please find the slides for tomorrow's meetings. Please let me know if you have any amendments or additions.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

APAR0000005341-2515420

Join Zoom Meeting

<https://fnih.zoom.us>

(b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

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US (New York)

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US (Chicago)

US (New York)

US (Germantown)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/16/2020 10:02:59 PM
To: Patel, Naimish /US [(b) (6)] Eric Hughes [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] (b) (6) [(b) (6)] (b) (6) [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]
Subject: RE: Time Sensitive: Review and Feedback Needed for Agent Prioritization Subgroup

Thanks, Naimish!

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Patel, Naimish /US < (b) (6) >
Sent: Thursday, April 16, 2020 5:48 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) > Eric Hughes < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Ruxandra Draghia-Akli < (b) (6) > Mellors, John W < (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Young, John < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Poole, Mike < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Vincent, Michael < (b) (6) >
Cc: Elizabeth Kim < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Alvarez, Rosa Maria < (b) (6) > Salathin, Carla < (b) (6) > (b) (6) < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Melencio, Cheryl (FNIH) [T] < (b) (6) > Lucas Smalldon < (b) (6) >
Subject: Time Sensitive: Review and Feedback Needed for Agent Prioritization Subgroup

Dear Stacey,

The prioritization criteria look very good to me – no suggested changes.

I wish to participate in the agent prioritization process.

APAR0000023403-2515421

Area of expertise: Board certified Pulmonologist, Critical Care Physician. Background in Immunology, translational medicine, and clinical development.

Best wishes,
Naimish

From: "Adam, Stacey (FNIH) [T]" <(b) (6)>
Date: Thursday, April 16, 2020 at 4:50 PM
To: Eric Hughes <(b) (6)>, "Read, Sarah (NIH/NIAID) [E]" <(b) (6)>, Ruxandra Draghia-Akli <RD (b) (6)>, "Mellors, John W" <(b) (6)>, "Patel, Naimish /US" <(b) (6)>, "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)>, "Young, John" <(b) (6)>, "Stein, Peter (FDA/CDER)" <(b) (6)>, "Poole, Mike" <(b) (6)>, "Buchman, Tim (OS/ASPR/BARDA) (CTR)" <(b) (6)>, "Vincent, Michael" <(b) (6)>
Cc: Elizabeth Kim <(b) (6)>, "Menetski, Joseph (FNIH) [T]" <(b) (6)>, "Alvarez, Rosa Maria" <(b) (6)>, "Salathin, Carla" <(b) (6)>, <(b) (6)>, "Parker, Ashley (NIH/OD) [E]" <(b) (6)>, "Wholley, David (FNIH) [T]" <(b) (6)>, "Melencio, Cheryl (FNIH) [T]" <(b) (6)>, Lucas Smalldon <(b) (6)>
Subject: [EXTERNAL] Time Sensitive: Review and Feedback Needed for Agent Prioritization Subgroup

EXTERNAL : Real sender is (b) (6)

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

First, thank you all for attending the WG call today. As discussed, please find attached again the DRAFT Prioritization Criteria broken out into data fields in this Excel spreadsheet. We really would like to hear your feedback on these fields and if they are the right ones and comprehensive.

Second, we have decided that if we can get response from at least 75% of you by 6am tomorrow (04/16/2020) on this document that we will not have a need to meet tomorrow, but can regroup again on Monday. Until then I am placing a **HOLD on your calendar for the meeting**. Therefore, if you could please email me that you have reviewed this document and let me what your feedback is. **Please respond, even just to say no changes or looks good.**

Finally, the co-chairs have begun to discuss how we should find individuals to perform the review. **We envision that we will need specific areas of expertise based on our first WG conversation; therefore, please let us the answer to the following two questions:**

1. **Do you wish to participate in the agent prioritization process? YES/NO**
2. **If yes, could you please provide us with what you feel your specific expertise is?**

This second question will allow us to determine we need to recruit other reviewers. We do envision segmenting the lists into small groups for review initially based on expertise and agents. Then we would have those smaller groups report to the larger team for final prioritization assessment.

Thanks again for all your efforts!

Kind regards,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/18/2020 2:10:43 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Bascles, Lionel [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael [(b) (6) Desrosiers, Betsy [(b) (6)]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lucas Smalldon [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Kelly Beazley [(b) (6) Wung, Peter /US [(b) (6)]
Subject: Follow-up to ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting
Attachments: 2020-04-16_TX-Clinical_WG_Master_Protocols_Subgroup_Summary.pdf

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you all for your incredible help this week. I hope you all have a nice weekend and are able to get some rest!

Please find attached the final formal summary of our 2nd Subgroup call. Please review and let me know if you have any additions or amendments.

The co-chairs, subgroup chair, and I will be hard at work over the weekend on some materials. We look forward to sharing them with you all on Monday for our continued discussion. Please do not hesitate to reach out if you have any questions in the meantime!

Thanks,
Stacey

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